# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## Investigation the effect of multimodal standard nursing program (MSNP) in lymphedema and self-efficacy after mastectomy surgery of breast cancer patients

## Protocol summary


**Study aim**

Determining the effect of multimodal standard nursing program (MSNP) in lymphedema and self-efficacy after mastectomy in patients with breast cancer.

**Design**

A clinical trial with a control group, with parallel groups, without blinding, randomized using a block method, phase three on 102 patients. Time block method is used for randomization.

**Settings and conduct**

This study will be conducted on breast cancer patients after radical mastectomy who are referred to Omid and Imam Reza hospitals in Mashhad. The intervention will include six weekly multimodal training sessions by nurses over a period of six weeks. During these sessions, education will be provided on nutrition, lymphedema prevention exercises, and psychological and social support.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: women with breast cancer, radical mastectomy surgery, two days to three months after mastectomy surgery, no diagnosis of lymphedema, age between 18 and 60 years, and willingness to participate in the study. Exclusion criteria: non-participation in one or more nursing training sessions, presence of upper limb musculoskeletal disorders and upper limb infection or wound, initiation of chemotherapy and radiotherapy treatment, failure to complete research questionnaires, and withdrawal from the study.

**Intervention groups**

The intervention includes the implementation of multimodal educational sessions by the nurse for six sessions will be carried out on a weekly basis during six weeks. At the same time as the intervention group, the control group receives routine training programs of the hospital, which are taught in the health clinic of Omid and Imam Reza hospitals.

**Main outcome variables**

The amount of lymphedema and self-efficacy after mastectomy surgery of patients with breast cancer before the intervention, immediately after its completion and after two weeks the end of the intervention


## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20241221064120N1**
Registration date: **2025-03-12, 1403/12/22**
Registration timing: **prospective**

Last update: **2025-03-12, 1403/12/22**
Update count: **0**

**Registration date**

2025-03-12, 1403/12/22

**Registrant information**


**Name**

Elahe Safari

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 51 3726 1230

**Email address**

safariel3@mums.ac.ir


**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2025-04-09, 1404/01/20

**Expected recruitment end date**

2025-06-20, 1404/03/30

**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Investigation the effect of multimodal standard nursing program (MSNP) in lymphedema and self-efficacy after mastectomy surgery of breast cancer patients

**Public title**
Investigation the effect of multimodal standard nursing program (MSNP) in lymphedema and self-efficacy after mastectomy surgery of breast cancer patients
**Purpose**
Prevention
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Breast cancer diagnosis Age between 18 and 60 years Having radical mastectomy surgery Two days to three months passed after surgery No diagnosis of lymphedema Willingness to participate in the study
**Exclusion criteria:**
Failure to participate in one or more nursing training program sessions Musculoskeletal disorders of the upper limbs Having an infection or wound of the upper limbs Start chemotherapy and radiotherapy treatment Failure to complete research questionnaires Announcing withdrawal from the research
**Age**
From **18 years** old to **60 years** old
**Gender**
Female

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **102**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
The patients are divided into 2 groups using the time block of 34 people randomly allocated using the Sealed envelope website and the groups are named A and B respectively, so that A group will receive multimodal training and B group will receive routine hospital training. The benefit of this method is that the volume of each block must be determined based on the time of visiting the hospital (block of three). Then the list of blocks is written and numbers are assigned to them, then random numbers between 1 to 6 (for example, 1, 4, 5, etc.) are selected and the numbers are placed in sealed envelopes, and people randomly pick the envelopes and continue until the final sample size is reached.(Odd numbers include the intervention group and even numbers include the control group).
**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 Mashhad University of Medical Sciences
**Street address**
Deputy for Research and Technology, Qorashi Building, next to Hoveyzeh Cinema, Daneshgah Ave, Mashhad
**City**
Mashhad
**Province**
Razavi Khorasan
**Postal code**
9194687367
**Approval date**
2025-01-21, 1403/11/02
**Ethics committee reference number**
IR.MUMS.NURSE.REC.1403.086

## Health conditions studied

### 1

**Description of health condition studied**
Lymphedema after Mastectomy in breast cancer
**ICD-10 code**
I97.2
**ICD-10 code description**
Postmastectomy lymphedema

## Primary outcomes

### 1

**Description**
The extent of lymphedema after mastectomy in patients with breast cancer
**Timepoint**
before the start of the intervention, immediately after its completion (primary) and after two weeks after the end of the intervention (secondary)
**Method of measurement**
Q-DASH (standardized Q-DASH) and arm circumference measurement method (by measuring 10 cm above the wrist and 10 cm above the elbow of both limbs and the difference in arm circumference of the two limbs is more than 2 cm)

**2**

**Description**
The level of self-efficacy after mastectomy surgery of patients with breast cancer
**Timepoint**
before the start of the intervention, immediately after its completion (primary) and after two weeks after the end of the intervention (secondary)
**Method of measurement**
Chronic Disease Self-Efficacy Questionnaire (CDSES)

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: patients with breast cancer after radical mastectomy referred to Omid and Imam Reza teaching hospitals in Mashhad. Intervention: multifaceted nursing training sessions (physical, psychological and social) in six one-hour sessions over six weeks
**Category**
Prevention

**2**

**Description**
Control group: breast cancer patients after radical mastectomy referred to teaching hospitals in Mashhad, who receive the hospital's routine educational content regarding lymphedema and improving self-efficacy.
**Category**
Prevention

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Omid Hospital
**Full name of responsible person**
Elahe Safari
**Street address**
Omid Hospital, AlNandasht Square, Kohsangi St.
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**Postal code**
9194687367
**Phone**
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**Email**
safariel3@mums.ac.ir

**2**

**Recruitment center**
**Name of recruitment center**
Imam Reza hospital
**Full name of responsible person**
Elahe Safari
**Street address**
Imam Reza Hospital, Imam Reza Square, Ibn Sina Street., Imam Reza Square
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Mashhad University of Medical Sciences
**Full name of responsible person**
Abbas Heidary
**Street address**
Mashhad University of Medical Sciences, Olom blvd, Pardis, Vakil abad blvd, Mashhad
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**Province**
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**Phone**
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**Email**
HeidaryA@mums.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Mashhad 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**
Mashhad University of Medical Sciences

**Full name of responsible person**
Elahe Safari

**Position**
Student

**Latest degree**
Bachelor

**Other areas of specialty/work**
Nursery

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Block 52, Shahid Karimi 4,6 Ave, Shahid Karimi Blvd.

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## Person responsible for scientific inquiries

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**Latest degree**
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Nursery

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## Person responsible for updating data

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**Full name of responsible person**
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**Latest degree**
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**Other areas of specialty/work**
Nursery

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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**
The data includes age and gender, the incidence of lymphedema, and the self-efficacy of the intervention group and the control group.

**When the data will become available and for how long**
The access period starts six months after the publication of the results

**To whom data/document is available**
People working in academic and scientific institutions as well as people working in industry

**Under which criteria data/document could be used**
People who need data for research and scientific work.

**From where data/document is obtainable**
Elahe safari safariel3@mums.ac.ir

**What processes are involved for a request to access data/document**
First, they will email me the request and the reason for it, and then after checking and confirming her reasons, the data will be emailed to her.

**Comments**