Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

Effects of relaxation techniques on edema volume, anxiety, and depression in women receiving complete decongestive therapy for lymphedema

Protocol summary

Summary

This study investigated the effects of relaxation techniques on the volume of edema, anxiety, and depression in women receiving complete decongestive therapy (CDT) for lymphedema. This quasi-experimental clinical trial was conducted on 31 women in two groups of control (n = 16) and intervention (n = 15). Women were only recruited if they had postmastectomy lymphedema (edema volume > 200 cc) and scored eight or higher on the Hospital Anxiety and Depression Scale. Despite the absence of a randomization technique in this single-center study, the two groups had no significant differences in age, body mass index, duration of edema, and number of removed and involved lymph nodes.Study is single blind because evaluator and analyzer don’t know to each person in which group. The first phase of treatment in the control group included 60-minute sessions of CDT, six days a week, for three weeks. Each session consisted of manual lymphatic drainage, multilayer compression bandaging, rehabilitation exercises, and skin and nail care. During the second phase, the same methods were continued and the patients were asked to wear arm-sleeves every day. The intervention group was then treated. They received 30 minutes of progressive muscle relaxation before each CDT session. They were also orally instructed to perform muscle relaxation, which resulted in the relaxation of 16 large skeletal muscle groups. A person (not involved in this study) measured the volume of edema, depression, and anxiety at the beginning of the study, after the first phase (third week), and after the follow-up period (ninth week).

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2014111019891N1**
Registration date: **2015-10-22, 1394/07/30**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-10-22, 1394/07/30

Registrant information

Name

shahpar Haghighat

Name of organization / entity

Breast Cancer Research Center, ACECR

Country

Iran (Islamic Republic of)

Phone

+98 21 8867 7578

Email address

sh.haghighat@ibcrc.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2012-06-30, 1391/04/10

Expected recruitment end date

2014-04-30, 1393/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of relaxation techniques on edema volume, anxiety, and depression in women receiving complete decongestive therapy for lymphedema

Public title
The effect of relaxation on lymphedema volume, anxiety and depression in post mastectomy lymphedema
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: Unilateral Breast cancer; completed surgery and adjuvant treatment; Scar healing ; Edema volume > 200cc; HADS >8 Exclusion Criteria: withdrawal ; severe fibrotic tissue ; Become metastatic Underlying disease .
Age
No age limit
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **31**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Single 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 Shahid Beheshti University of Medical Sciences
Street address
Shahid Beheshti University of Medical Sciences
City
Tehran
Postal code
Approval date
2014-03-02, 1392/12/11
Ethics committee reference number
14942

Health conditions studied

1

Description of health condition studied
breast cancer
ICD-10 code
C50
ICD-10 code description
Malignant neoplasm of breast

2

Description of health condition studied
Lymphedema
ICD-10 code
I97.2
ICD-10 code description
Postmastectomy lymphedema syndrome

Primary outcomes

1

Description
Edema volume
Timepoint
Before treatment,3 weeks after treatment,9 weeks after treatment
Method of measurement
Water displacement volumetry

2

Description
Anxiety
Timepoint
Before treatment,3 weeks after treatment,9 weeks after treatment
Method of measurement
Hospital Anxiety and Depression Scale

3

Description
Depression
Timepoint
Before treatment,3 weeks after treatment,9 weeks after treatment
Method of measurement
Hospital Anxiety and Depression Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: CDT+ Progressive Muscle Relaxation(30 min in 6 day for 3 weeks & CDT)
Category
Treatment - Other

2

Description
Control group:CDT(60 minutes , six days a week, for three weeks)
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Seyedkhandan Physiotherapy Institute
Full name of responsible person
Shahpar Haghighat
Street address
Unit4, 2nd floor, No.17, Abuzar Ghaffari St, Seyedkhandan Ave.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Investigator
Full name of responsible person
Shahpar Haghighat
Street address
No146, Gandi St, Haghani St
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Investigator
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Breast Cancer Research Center, ACECR
Full name of responsible person
Shahpar Haghighat
Position
Research Assistant Professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty