

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

The Comparison between the effect of online and face to face resistance training with manual therapy and mobilization on pain, range of motion, lymphedema, depression, body image and shoulder function in breast cancer survivors.

Protocol summary

Study aim

The aim of this study is the Comparison of the effect of online and face to face resistance training with manual therapy and mobilization on pain, range of motion, lymphedema, depression, body image and shoulder function in breast cancer survivors.

Design

This research, because of two intervention group and one control group is quasi- experimental and clinical trial and research design is pre and post test, a blinded study and randomize control trial. 42 participants will be recruited and loss of participants will be 20%.

Settings and conduct

In this study, participants will be recruited from Gerash hospital with insert Announcement and they will be examined by physician. Before training process, participants will be assigned consent form. Eventually, after pre test experiment groups will be executed training self-specific protocol for six weeks and three sessions at per week, while control group will be continued to their routine activity daily live. It is saying that training protocol will be executed in Amirolmomenin gym.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women that survive from breast cancer in 30 to 50 age. Lack of cardiovascular disease. 6 to 12 month after their surgery, Chemotherapy and Radiotherapy. Exit criteria: Smoking and alcohol usage. Disease recurrent and presence of injury during intervention process. 2 consecutive sessions or 3 interval session absence in training process. Lack of intention to taking part in thesis process.

Intervention groups

Group of online and in person resistance training with manual therapy Group of mobilization

Main outcome variables

Pain, Range of motion, depression, lymphedema, body image and shoulder function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230415057913N1**

Registration date: **2023-05-08, 1402/02/18**

Registration timing: **prospective**

Last update: **2023-05-08, 1402/02/18**

Update count: **0**

Registration date

2023-05-08, 1402/02/18

Registrant information

Name

Fereshteh Ghorbani

Name of organization / entity

Kharazmi University of Tehran

Country

Iran (Islamic Republic of)

Phone

+98 71 5244 0054

Email address

alifreshfrifit@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-11, 1402/02/21

Expected recruitment end date

2023-07-12, 1402/04/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison between the effect of online and face to face resistance training with manual therapy and mobilization on pain, range of motion, lymphedema, depression, body image and shoulder function in breast cancer survivors.

Public title

The Comparison between the effect of online and face to face resistance training with manual therapy and mobilization on pain, range of motion, lymphedema, depression, body image and shoulder function in breast cancer survivors.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

- Women survived from breast cancer in 30 to 50 age.
- Lack of cardiovascular disease.
- 6 to 12 month past their surgery, Chemotherapy and Radiotherapy.

Exclusion criteria:

- Smoking and alcohol usage.
- Disease recurrent and presence of injury during intervention process.
- 2 consecutive sessions or 3 interval session absence in training process.
- Lack of intention to taking part in thesis process.

AgeFrom **30 years** old to **50 years** old**Gender**

Female

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample sizeTarget sample size: **42****Randomization (investigator's opinion)**

Randomized

Randomization description

In this thesis, 42 participants will be recruited and They randomly assigned into a control group and two experimental group then, for randomization assignment, coding boxes with random order will be used so that, their size and forms are similar. This process is individually and sealed envelope will be used to randomization so that one number is assigned to a person. Number one will be assigned to resistance training +manual therapy group, number two will be assigned to mobilization group ,and number three will be assigned to control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this research, participants will be divided into two experimental groups and a control group. At first, They will be informed about research process generally But, They will not informed about research details such as; objectives. In exert phases, the first and second intervention group will be separated then others. Data analysis will be implemented by statistic data analysis specialist so that he/she will be received statistical data.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kharazmi Univercity.

Street address

Shahid Keshvari complex, South Razan st, Mirdamad Endway. Physical education and Sport Science Faculty, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1587958711

Approval date

2023-02-19, 1401/11/30

Ethics committee reference number

IR.SSRC.REC.1401.153

Health conditions studied**1****Description of health condition studied**

Women who is survived from breast cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes**1****Description**

Pain

Timepoint

Pre and post test

Method of measurement

Visual Analog Scale

2

Description

Range of Motion

Timepoint

Pre and post test

Method of measurement

Goniometer

3

Description

Lymphedema

Timepoint

Pre and post test

Method of measurement

Lymphedema Volume meter

4

Description

Depression

Timepoint

Pre and post test

Method of measurement

Depression Test

5

Description

Body Image

Timepoint

Pre and post test

Method of measurement

Body Image Questionnaire

6

Description

shoulder function

Timepoint

Pre and post test

Method of measurement

Y Balance tes

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this study, the First intervention group (resistance training + manual therapy) will be executed 6 weeks and 3 sessions per week for 60 min integrated online and in person training. The researcher 1 session will be assigned 1 session to in person training and 2 sessions will be assigned to online training. In this thesis, resistance training will be executed by ACSM guideline included flexors, abductors and external rotators of upper body muscles strengthening. Warm up

will be performed for 5 min after and before of training. Training in first and second week will be performed by 8 to 12 repetitions with 2 sets, training in third and fourth week by 8 to 12 repetitions with 3 sets and eventually, fifth and sixth week by 8 to 12 repetitions with 4 sets.

Category

Rehabilitation

2

Description

Intervention group: Second intervention group (manual therapy) will be executed 6 weeks mobilization with Dr. Dias protocol for scapula and shoulder joint. Thus, for prevention of lymphedema in breast, thorax and other portions of included upper limb body, PNF and scar tissue massage will be executed orderly assist and passive movement and then, active and assist active movement with patients education.

Category

Rehabilitation

3

Description

Control group: the control group will not be do any intervention.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

The Gerash Amir Ali Momenin educational and Therapeutic Center.

Full name of responsible person

Fereshteh ghorbani

Street address

Baran Alley, Vahdat St, Sheikh Ahmed Ansari St, Gerash City, Iran.

City

Gerash

Province

Fars

Postal code

74417636840

Phone

+98 71 5244 0054

Email

alifreshfrifit@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kharazmi university

Full name of responsible person

Amir Letafat Kar

Street address

Sport Science Faculty, Shahid Keshvari Complex,
South Razan St, Mirdamad St

City

Karaj

Province

Tehran

Postal code

439815875

Phone

+98 21 2222 8001

Email

letafatkaramir@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kharazmi university

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

Kharazmi University

Full name of responsible person

Fereshteh Ghorbani

Position

Mater of Student

Latest degree

Bachelor

Other areas of specialty/work

Sport Medicine

Street address

Baran Alley, Vahdat St, Sheikh Ahmed Ansari St,
Gerash City, Fars United, Iran.

City

Gerash

Province

Fars

Postal code

7441763684

Phone

+98 71 5244 0054

Email

alifreshfrifit@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kharazmi University

Full name of responsible person

Fereshteh Ghorbani

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Mater of Student

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Email

alifreshfrifit@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Kharazmi University

Full name of responsible person

Fereshteh Ghorbani

Position

Mater of Student

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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
only a part of data as a mean is shared with a paper.
When the data will become available and for how long

September 2023
To whom data/document is available
The information is confidential and available for all as a paper
Under which criteria data/document could be used
the information is confidential and available for all as a paper
From where data/document is obtainable
Fereshteh ghorbani
What processes are involved for a request to access data/document
2 months later of publish, data will be sent by email
Comments