

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Comparison of the therapeutic effectiveness of telebiofeedback and conventional shoulder physiotherapy methods on improving the quality of life of breast cancer patients with a history of mastectomy

Protocol summary

Study aim

Investigating the effectiveness of shoulder telebiofeedback in improving the quality of life of mastectomy patients and then comparing new method with conventional physiotherapy to determine the best supportive treatment to be used in treatment and support centers.

Design

This study is a clinical trial type with a control group with parallel and randomized groups in three phases on 60 patients and Joule random numbers are used for randomization.

Settings and conduct

Eligible samples are selected from clinic patients of Rasool Akaram and Firoozgar hospital. The intervention group will undergo biofeedback therapy for 2 months, 2 sessions per week in the first month and one session per week in the second month and each session lasts 20 minutes. The control group will undergo physiotherapy with the same treatment plan. It is not possible to blind patients and therapists. The assessor is blinded in the assessment phase.

Participants/Inclusion and exclusion criteria

Inclusion criteria : • Women over 18 and under 65 with breast cancer who have undergone mastectomy.
Exclusion criteria; • Metastatic patients • Pregnancy • History of trauma to the shoulder and neck area • Cognitive disorders • Radiation • Leaving Tehran • Death of patients • The patient's unwillingness to intervene. • Any previous dysfunction of the hands (burn, previous injury that causes dysfunction).

Intervention groups

Breast cancer patients who underwent mastectomy will be evaluated in the telebiofeedback intervention group and the effectiveness of physiotherapy in the control group.

Main outcome variables

quality of life in breast cancer patients with history of mastectomy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220814055691N1**

Registration date: **2022-10-09, 1401/07/17**

Registration timing: **registered_while_recruiting**

Last update: **2022-10-09, 1401/07/17**

Update count: **0**

Registration date

2022-10-09, 1401/07/17

Registrant information

Name

Mozhde Mohammadpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8214 1229

Email address

mohammadpour.mo@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-05, 1401/06/14

Expected recruitment end date

2023-09-05, 1402/06/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the therapeutic effectiveness of telebiofeedback and conventional shoulder physiotherapy methods on improving the quality of life of breast cancer patients with a history of mastectomy

Public title
tele biofeedback and shoulder physiotherapy effectiveness on the quality of life of breast cancer patients with a history of mastectomy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Women over 18 and under 65 years old with breast cancer who have undergone radical mastectomy modification.
Exclusion criteria:
 metastatic cancer pregnancy history of trauma to neck and upper limb cognition impairment radiation leaving Tehran Death reluctance to intervention any previous dysfunction in shoulder function

Age
From **18 years** old to **65 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization method will be simple, which is done by the random numbers table method The table of random numbers is a set of numbers without a specific pattern and order, which is determined to read the numbers first, and in this study, even numbers will be telebiofeedback and odd numbers will be physiotherapy. Due to the fact that the sampling is done in a multi-centered manner, the method of concealment is done centrally, and the participants' entry into the study is done by phone call to the Firuzgar center.

Blinding (investigator's opinion)
Single blinded

Blinding description
Patients were evaluated by a separate researcher who did not participate in the selection and treatment of patients and was blind to the procedure.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Iran University of Medical Sciences.

Street address

Valiasr Square, Beh Afarin Street, Firouzgar Hospital.

City

tehran

Province

Tehran

Postal code

1593748711

Approval date

2022-06-19, 1401/03/29

Ethics committee reference number

IR.IUMS.REC.1401.275

Health conditions studied

1

Description of health condition studied

breast cancer

ICD-10 code

D05

ICD-10 code description

Carcinoma in situ of breast

Primary outcomes

1

Description

Quality of life in qlqc30 questionnaire.

Timepoint

The intervention is measured in weeks 0, 4, and 12 after intervention

Method of measurement

Based on Quality of Life Questionnaire-Core 30 (QLQC30) questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group (telebiofeedback) which is a specific type of physiotherapy for the shoulder joint and muscles in which the surface electrodes are placed on the patient's

skin in specific areas and record the electrical activity of certain muscles based on the location. Patients are first trained on how to use the device, These people will be given the necessary explanations on how to communicate with the doctor/therapist. For 2 months, 2 sessions per week in the first month and 1 session per week in the second month and each session for 20 minutes underwent shoulder muscle biofeedback therapy to strengthen weakened muscles And the necessary muscle relaxation is based on the initial assessment and established protocols. In these sessions, the doctor/therapist is present online And according to the access to the biofeedback program and the results obtained from it, it controls and reviews the sports. During the sessions, the therapist determines the intensity and frequency of the exercises that the patient should do according to the progress of the patient and the frequent evaluations he performs before, during and after the session.

Category

Rehabilitation

2

Description

Control group: In the control group, patients are subjected to conventional shoulder physiotherapy for 2 months, 2 sessions per week in the first month and one session per week in the second month, and each session lasts 20 minutes, based on the mentioned protocols. In the control group, the same patients for 2 months, 2 sessions per week in the first month and one session per week in the second month and each session for 20 minutes under conventional shoulder physiotherapy which includes electrical stimulation methods, infrared rays and ultrasound and training Sports will be included. In both cases, due to the nature of sports, the patient will not be deprived of the minimum necessary measures and will not cause a disturbance in the patient's recovery process.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool Akram Hospital

Full name of responsible person

Mozhdeh Mohammadpour.

Street address

Sattar Khan St, Niayesh St, corner of Mansouri St, Rasoul Akram Hospital.

City

tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6435 1000

Email

Rasoolhospital@iums.ac.ir

Web page address

<https://hrmc.iums.ac.ir/>

2

Recruitment center

Name of recruitment center

Firouzgar Hospital

Full name of responsible person

Mozhdeh Mohammadpour.

Street address

Valiasr Square, Beh Afrin St, Firouzgar Hospital

City

tehran

Province

Tehran

Postal code

1593748711

Phone

+98 21 8214 1000

Email

firoozgarhospital1@gamil.com

Web page address

<https://firoozgar.iums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

dr.hossien keyvani

Street address

hemmat highway . iran university of medical science

City

tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 2504

Email

keyvani@hiums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Phone

+98 21 8214 1229

Email

bforough@tums.ac.ir

Person responsible for general inquiries**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Mozhde mogammadpour

Position

PMR resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

Street address

behafrin ave. valiasr squer firozgar hospital

City

tehran

Province

Tehran

Postal code

1593748712

Phone

+98 21 8214 1229

Email

mozhde.mohammadpour73@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

mozhde mohammadpour

Position

PMR resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

Street address

Behafarin Ave, Valiasr square.Firozgar hospital

City

Tehran

Province

Tehran

Postal code

1593748711

Phone

+98 21 8214 1229

Email

mozhde.mohammadpour73@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

bijan forough

Position

professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

Street address

behafrin ave.valiasr square firozgar hospital

City

tehran

Province

Tehran

Postal code

1593748711

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