

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of motor exercises on quality of life, depression and anxiety in women with breast cancer

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

The effect of motor exercises on quality of life, depression and anxiety in women with breast cancer

Design

First, both control and experimental groups complete the questionnaires as pre-test. According to inclusion and exclusion criteria, they are randomly divided into two groups. The written consent of the research participant is obtained. Both groups will then undergo a 6-minute walk test and shoulder joint test. The intervention is then followed by 5 weeks of regular walking and arm movements. At the end of 5 weeks, both groups will receive post-test.

Settings and conduct

The study is a randomized controlled clinical trial at Imam Khomeini Hospital in Sari.

Participants/Inclusion and exclusion criteria

Inclusion: Women with non-metastatic non-postmenopausal breast cancer, over 18 years old, one or both breast discharges Exclusion: Subject's unwillingness to continue the intervention

Intervention groups

Questionnaires will be completed by the oncology surgeon, followed by a 6-minute walk test and shoulder joint range of motion measurements. The motor exercises used for the intervention group are selected in consultation with the sports medicine specialist and the patient's physician. And the intervention is a 5-week regular walk and arm movements.

Main outcome variables

Quality of life, depression, anxiety

Last update: **2020-04-03, 1399/01/15**

Update count: **0**

Registration date

2020-04-03, 1399/01/15

Registrant information

Name

Iran Ghasemi Cherati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-07, 1398/07/15

Expected recruitment end date

2020-05-19, 1399/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of motor exercises on quality of life, depression and anxiety in women with breast cancer

Public title

The effect of motor exercises on quality of life, depression and anxiety in women with breast cancer

Purpose

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200228046637N1**

Registration date: **2020-04-03, 1399/01/15**

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
women with breast cancer Non-metastatic non-postmenopausal over 18 years of age at least literate one or both breast drains The drain has been removed no psychological treatment experience no drug addiction No heart disease No respiratory disease no history of regular physical activity one year prior to the study patient consent to participate in research and written consent

Exclusion criteria:
Subject's unwillingness to continue the intervention physical disability of the intervention due to treatment periods Unable to walk Unable to stand People with a HADS questionnaire score of less than 11.

Age
From **18 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Subjects are numbered on entry to the treatment center and will be assigned to one of the intervention or control groups using random numbers table and simple randomization method.

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

Imam Educational Hospital of Sari-Mazandaran
University of Medical Sciences

Street address

Sari-Shahband Street-Vesal square-Nasibeh School of
Nursing and Midwifery

City

Sari

Province

Mazandaran

Postal code

4816715793

Approval date

2018-12-19, 1397/09/28

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1397.062

Health conditions studied

1

Description of health condition studied

breast cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

Quality of Life

Timepoint

Before intervention - 5 weeks later

Method of measurement

1) QLQ-C30 specific quality of life questionnaire and 2
quality of life questionnaire for breast cancer patients:
EORTC QLQ-C23.V.3

2

Description

depression and anxiety

Timepoint

Before intervention - 5 weeks later

Method of measurement

HADS Hospital Expression and Anxiety Questionnaire

Secondary outcomes

1

Description

Level of physical fitness

Timepoint

Before surgery, after drainage, 5 weeks later

Method of measurement

6 minute walk test

2

Description

Joint angles and axis view of joint motion

Timepoint

Goniometer

Method of measurement

Before surgery, after drainage, 5 weeks later

Intervention groups

1

Description

Intervention group: Depression, quality of life and demographic questionnaires will be completed as a pre-test. The written consent of the research firm is obtained from them. Motion training is provided by a research associate (sports medicine specialist). Then a 6-minute walk test is performed for the patients to assess their fitness level and to measure shoulder joint range of motion with goniometer. The exercises that are used are selected in consultation with a specialist in sports medicine and patients. The intervention will then be administered to the patients for a 5-week regular walk and arm movements with pamphlets. Arm exercises begin on the second day after surgery and are performed 3 times a week for 20 minutes each time for 5 weeks. If the patient feels uncomfortable, taking a warm shower before exercise can also reduce joint stiffness and ease. Subjects are told that there is no compulsion to continue activities during the sessions and that they can be discouraged if they experience slight fatigue and unpleasant feelings. After the training, the post-test will also be repeated to assess the difference between the groups and the impact of the interventions.

Category

Rehabilitation

2

Description

Control group: First, the goals of the research will be explained to them, and then as a pre-test, they will complete the Depression, Quality of Life and Demographic Questionnaires. Based on the results of the questionnaires and according to the inclusion and exclusion criteria of the eligible people, they are randomly assigned to the control group. They are asked not to participate in any organized exercise program during this time. After 5 weeks, they will be tested again to assess the difference between the groups. At the end of the intervention, participants will be instructed on the ethical considerations of walking and arm movements. And a pamphlet is given to them.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Seyed Hamzeh Hosseini

Street address

Sari-Shahband Street-Vesal square-Nasibeh School of Nursing and Midwifery

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Email

fahime.ghasemi24@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saeedi

Street address

Sari-Shahband Street-Vesal square-Nasibeh School of Nursing and Midwifery

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+98 11 3335 2725

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fahime.ghasemi24@gmail.com

Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sari 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

Mazandaran University of Medical Sciences

Full name of responsible person

Fahimeh Ghasemi Cherati

Position

MSC.Lecturer, Department of Medical Surgery Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

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Sari-Shahband Street-Vesal square-Nasibeh School of Nursing and Midwifery

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

Mazandaran University of Medical Sciences

Full name of responsible person

Vida Shafipour

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Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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

Mazandaran University of Medical Sciences

Full name of responsible person

Fahimeh Ghasemi Cherati

Position

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Latest degree

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Other areas of specialty/work

Nursery

Street address

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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

Primary and secondary outcome information is shared anonymously.

When the data will become available and for how long

Access started 6 months after the results were published.

To whom data/document is available

Accessible to all researchers working in academic institutions and specialists in breast surgery

Under which criteria data/document could be used

The results of documentation and data can be used for or not to be used on breast surgery patients.

From where data/document is obtainable

The person responsible for the public accountability of the study can provide information to eligible individuals. Fahimeh Qasemi Cherati, fahime.ghasemi24@gmail.com

What processes are involved for a request to access data/document

If the person is eligible to request access to the documentation, it will be attempted to provide it as soon as possible after it has been demonstrated that the person is authorized to access the data.

Comments

I hope that the results of the research will help improve the condition of patients.