

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effects of resistance exercise on pain, fatigue and mobility in breast cancer survivors

Protocol summary

Study aim

The objective of this study is to assess the effects of resistance exercise on pain and fatigue, mobility, and muscle mass preservation in breast cancer patients.

Design

Single blinded. Assessor will be unaware of the intervention (intervention or control). status This study is a randomized controlled trial Participants will be assigned to either the intervention group (resistance exercise) or the control group (usual care) by computer generated Baseline measurements of pain, fatigue, mobility and muscle mass will be recorded. At the midpoint of the intervention period pain, fatigue, mobility, and muscle mass will be reassessed for both groups. At the end of the 6-week intervention, final measurements of pain, fatigue, mobility, and muscle mass will be obtained for both groups.

Settings and conduct

Data will be collected from Shaukat khanum hospital, Lahore and oncology department at University of Lahore teaching hospital (ULTH). Blinding Single blinded.

Participants/Inclusion and exclusion criteria

INCLUSION Age between 18 to 50 years. Breast Cancer survivors. Cancer survivors undergoing pain and moderate fatigue and had treatment with both chemotherapy and radiation therapies. **EXCLUSION** Recent orthopedic surgery. Active infections in cancer patients of grade III-IV

Intervention groups

Group A: participants receive standard care in this group
Group B: participants receive resistance exercises with respect to their conditions

Main outcome variables

Visual Analog Scale Multidimensional fatigue inventory questionnaire Timed Up and Go (TUG) test

Acronym

IRCT registration information

IRCT registration number: **IRCT20231103059935N1**

Registration date: **2023-11-25, 1402/09/04**

Registration timing: **prospective**

Last update: **2023-11-25, 1402/09/04**

Update count: **0**

Registration date

2023-11-25, 1402/09/04

Registrant information

Name

Ayesha Javed

Name of organization / entity

University of Lahore

Country

Pakistan

Phone

+92 313 8633199

Email address

ayeshajavedrao@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-30, 1402/09/09

Expected recruitment end date

2024-01-15, 1402/10/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of resistance exercise on pain, fatigue and mobility in breast cancer survivors

General information

Reason for update

Public title

Resistance exercise on pain, fatigue and mobility in breast cancer survivors`

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

• Breast Cancer survivors • Cancer survivors undergoing pain and moderate fatigue • Cancer survivors had treatment with both chemotherapy and radiation therapies • Age between 18 to 50 years

Exclusion criteria:

• Recent orthopedic surgery. • Active infections in cancer patients of grade III-IV i.e sepsis.

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants were randomly allocated into two groups through computer generated list. Simple randomization. Unit of randomization is individual and tool used in randomization is sealed envelopes. The use of sealed envelopes helps ensure that the treatment assignments are concealed until the last moment before the participant receives the treatment. This minimizes the risk of selection bias and ensures that the allocation process is not influenced by knowledge of upcoming assignments. The randomization process and envelope preparation are typically conducted by individuals who are not directly involved in participant enrollment or data collection to maintain the integrity of the study design.

Blinding (investigator's opinion)

Single blinded

Blinding description

Single blinded

Placebo

Not used

Assignment

Factorial

Other design features

Wall push-ups, Scapular squeeze, and Resistance bands exercises for resistance training

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research ethics committee of University of Lahore

Street address

1-Km Defence Road, near Bhuptian Chowk, Lahore, Punjab

City

Lahore

Postal code

54000

Approval date

2023-10-16, 1402/07/24

Ethics committee reference number

REC-UOL-544-10-2023

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

Pain

Timepoint

Before intervention ,3 and 6th weeks After intervention

Method of measurement

Visual analog scale

2

Description

Fatigue

Timepoint

Before intervention ,3 and 6th weeks after intervention

Method of measurement

Multidimensional fatigue inventory questionnaire

Secondary outcomes

1

Description

Mobility

Timepoint

Before intervention, 3 and 6 weeks after intervention

Method of measurement

Timed Up and Go (TUG) test

Intervention groups

1

Description

Intervention Group (Resistance Exercise): Participants will engage in a supervised resistance exercise program. Patient- tailored program of resistance exercise will be applied. The program will include a moderate to progressive series of resistance exercises targeting major muscle groups. Sessions will be conducted 2 times per week for 6 weeks. Each session will last 45 minutes, including warm-up, exercise, and cool-down. Exercise intensity and resistance will be adjusted based on individual capabilities and progress. Participants' pain, fatigue, and muscle mass will be closely monitored throughout the intervention.

Category

Rehabilitation

2

Description

Control Group (Standard Care): Participants will receive standard care, including medical treatments and recommendations provided by their healthcare providers. No specific exercise interventions will be introduced during the study period for this group.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

University of Lahore teaching hospital

Full name of responsible person

Dr. Asim Arif

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Lahore

Full name of responsible person

Dr. Ashfaq Ahmed

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Web page address

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Grant name

nil

Grant code / Reference number

nil

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

No

Title of funding source

University of Lahore

Proportion provided by this source

100

Public or private sector

Private

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

University of Lahore

Full name of responsible person

Ayesha javed

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Physiotherapy

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House no. 41, block C, Punjab government employees cooperative housing society, Phase 2, Lahore , Pakistan

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Latest degree
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Person responsible for updating data

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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

Demographic data and data related to final outcome will be shared by maintaining the confidentiality

When the data will become available and for how long

Data will be available from November 2024 to December 2024 after the 6 months of publication. The data sharing plan for a clinical trial(i.e. what data will be shared when and under what conditions)will be publicly available at a third-party site that shares data with and meets the data requirements of WHO's international clinical trail registry platform, this occur before the first participants is enrolled.

To whom data/document is available

Ayesha Javed(corresponding author) masters student at university of Lahore

Under which criteria data/document could be used

For research purpose

From where data/document is obtainable

To the corresponding author of the study, Dr. Ayesha Javed and can contact on +923006477662 ,ayeshajavedrao@gmail.com

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

Open access and there is the traditional public data release where anyone can get access to the data with no registration or conditions. The request will be reviewed by director in charge and in case of eligibility, it would be shared in two weeks

Comments

I want randomized clinical trial registration