

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

#### General information

##### Reason for update

##### 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

## 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

##### Street address

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

##### City

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##### Postal code

54000

##### Phone

+92 321 6597727

##### Fax

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##### Email

asim.arif@uip.t.uol.edu.pk

##### Web page address

<https://uol.edu.pk/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

University of Lahore

##### Full name of responsible person

Dr. Ashfaq Ahmed

##### Street address

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

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54000

##### Phone

+92 300 6477662

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##### Email

ayeshajavedrao@gmail.com

##### Web page address

<https://uol.edu.pk/>

##### 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

##### Street address

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

##### City

Lahore

##### Province

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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**  
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Student  
**Latest degree**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
University of Lahore  
**Full name of responsible person**  
Ayesha javed  
**Position**  
Student  
**Latest degree**  
Medical doctor  
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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