Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 envelops. 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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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

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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