Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effects of High-Intensity Versus Low-Intensity Resistance Training Along With Blood Flow Restriction in Patients with Total Knee Arthroplasty

Protocol summary

Study aim
This study aims to evaluate the effects of high-intensity versus low-intensity resistance training along with blood flow restriction on pain, range of motion, strength, muscle thickness, and functional performance in patients with total knee arthroplasty.

Design
parallel-group, single-blind, randomized clinical trial

Settings and conduct
Setting: Allied Hospital, Faisalabad single-blinded study. assessor will be blind.

Participants/Inclusion and exclusion criteria
INCLUSION CRITERIA • Both male and female patients • 50 to 65 years of age • Post-total knee arthroplasty for osteoarthritis • Unilateral joint replacement surgery EXCLUSION CRITERIA • Impaired cognitive function and mental disease (e.g., diagnosis of Alzheimer's disease) • Paraplegia/extremity amputation • End-stage renal disease requiring dialysis • Uncontrolled cardiovascular disease or Severe pulmonary disease • Active neoplasm • Body mass index greater than 40 kg/m² • Peripheral vascular disease or deep vein thrombosis • Opioid use and Chronic oral steroid use and anticoagulation use • Ipsilateral joint disease involving hip, ankle, or spine • Neurologic or other etiology of quadriceps wasting

Intervention groups
Both groups will receive the same baseline treatment. Group A: BFR with Low-Intensity Resistance training 5 min light cycling • Start with 10 repetitions of unliteral leg press at light weights • Calf raises • Knee flexion • Knee extension Progress to 20-30% of predicted 1RM Group B: BFR with High-Intensity Resistance training 5 min light cycling • Start with 10 repetitions of unliteral leg press at light weights • Calf raises • Knee flexion • Knee extension Progress to 65-70% of predicted 1RM

Main outcome variables
NPRS → Pain Universal goniometer → ROM Hand-held dynamometer → Strength Muscle mass → Ultrasound imaging Functional Performance • Lower extremity function scale • 6-Minute walk test

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190717044238N13**
Registration date: **2024-05-12, 1403/02/23**
Registration timing: **registered_while_recruiting**

Last update: **2024-05-12, 1403/02/23**
Update count: **0**

Registration date
2024-05-12, 1403/02/23

Registrant information

Name
Fareeha Amjad

Name of organization / entity
The University of Lahore

Country
Pakistan

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+92 42 99200600

Email address
fari_fairy22@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-05-06, 1403/02/17

Expected recruitment end date
2024-07-30, 1403/05/09

Actual recruitment start date
2024-05-12, 1403/02/23

Actual recruitment end date
2024-08-02, 1403/05/12

Trial completion date
2024-08-10, 1403/05/20

Scientific title
Effects of High-Intensity Versus Low-Intensity Resistance Training Along With Blood Flow Restriction in Patients with Total Knee Arthroplasty

Public title
Effects of resistance training in patients after total knee replacement surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Both male and female patients 50 to 65 years of age (27) Post-total knee arthroplasty for osteoarthritis Unilateral joint replacement surgery

Exclusion criteria:
Impaired cognitive function and mental disease (e.g., diagnosis of Alzheimer's disease) Paraplegia/extremity amputation End-stage renal disease requiring dialysis Uncontrolled cardiovascular disease or Severe pulmonary disease Active neoplasm Body mass index greater than 40 kg/m² Peripheral vascular disease or deep vein thrombosis Opioid use and Chronic oral steroid use and anticoagulation use Ipsilateral joint disease involving hip, ankle, or spine Neurologic or other etiology of quadriceps wasting

Age
From **50 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **34**
Actual sample size reached: **34**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization will be done by using computer generated randomizer. Allocation will be concealed by sealed envelope method.

Blinding (investigator's opinion)
Single blinded

Blinding description
This study will be a single blinded study. Assessor will be kept blind about the group allocation and previous readings.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research and ethics Commitee Riphah College of Rehabilitation and Allied Health Sciences

Street address
Riphah International University Gulberg campus lahore

City
Lahore

Postal code
54000

Approval date
2024-04-03, 1403/01/15

Ethics committee reference number
REC/RCR & AHS/23/0189

Health conditions studied

1

Description of health condition studied
Total knee arthroplasty

ICD-10 code
Z96.65

ICD-10 code description
Presence of artificial knee joint

Primary outcomes

1

Description
Pain

Timepoint
baseline , at 4th week and post training at 8th week

Method of measurement
Numeric Pain Rating Scale (NPRS)

2

Description
knee range of motion ROM

Timepoint
baseline , at 4th week and post training at 8th week

Method of measurement
Universal Goniometer

3

Description
Strength

Timepoint
baseline , at 4th week and post training at 8th week

Method of measurement
Hand-Held Dynamometer

4

Description
Quadriceps muscle thickness
Timepoint
baseline & at the end of 8th week
Method of measurement
Ultrasound Imaging

5

Description
Functional Performance
Timepoint
baseline , at 4th week and post training at 8th week
Method of measurement
a) Lower Extremity Function Scale b) 6-Minute Walk Test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:1BFR with Low Intensity Resistance training (For the first two weeks participants will follow home plan of standard physical therapy. Resistance training will be started if patient weight bears on unilateral leg for 5 s without support, have knee ROM of 0-90° able to perform repeated straight leg raise without knee extensor muscle lag. Patients 10 Repetition maximum (RM) will be used to predict 1 RM value according to formula 10 RM/ 0.75. BFR will be achieved using a tourniquet, and limb occlusion pressure (LOP) will be calculated, defined as the minimum pressure required for full arterial occlusion. Its will be calculated as baseline Systolic blood pressure (SBP) and formula for safety margins will be applied: add 40-50 mm Hg for SBP<130, Add 60-75 mm Hg for SBP 131-190, Add 80 mm Hg for SBP > 190. 60% of the calculated pressure will be used. Prior to exercise the cuff will be placed on the most proximal portion of the limb. -Standard Physical Therapy:1) Ankle Pumps2) AAROM/ AROM3) Quadriceps, Hamstrings and adductor setting Exercises 4) Patellar Mobilization (grade I, II) 5) Hamstrings, Calf & IT Band Stretching -Resistance Training:5 min light cycling• Start with 10 repetitions of unliteral leg press at light weights• Calf raises • Knee flexion• Knee extension. Progress to 20-30% of predicted 1RM
Category
Rehabilitation

2

Description
Intervention group: 2 BFR with High Intensity Resistance training (Resistance training will be started if patient weight bears on unilateral leg for 5 s without support, have knee ROM of 0-90° able to perform repeated straight leg raise without knee extensor muscle lag. Patients 10 Repetition maximum (RM) will be used to predict 1 RM value according to formula 10 RM/ 0.75. BFR will be achieved using a tourniquet, and limb occlusion pressure (LOP) will be calculated, defined as the minimum pressure required for full arterial occlusion. Its will be calculated as baseline Systolic blood pressure (SBP) and formula for safety margins will be applied: add 40-50 mm Hg for SBP<130, Add 60-75 mm Hg for SBP 131-190, Add 80 mm Hg for SBP > 190. 60% of the calculated pressure will be used. Prior to exercise the cuff will be placed on the most proximal portion of the limb. -Standard Physical Therapy:1) Ankle Pumps2) AAROM/ AROM3) Quadriceps, Hamstrings and adductor setting Exercises4) Patellar Mobilization (grade I, II)5) Hamstrings, Calf & IT Band Stretching -Resistance Training:5 min light cycling• Start with 10 repetitions of unliteral leg press at light weights• Calf raises • Knee flexion• Knee extension. Progress to 65-70% of predicted 1RM
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Allied Hospital, Faisalabad
Full name of responsible person
Maira Shahzad
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38000
Phone
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Email
help@ahfsd.pk
Web page address
https://ahfsd.pk/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Riphah International University Lahore
Full name of responsible person
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Street address
Riphah International University Gulberg campus lahore
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Phone
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Email
fari_fairy22@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Riphah International University 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
Riphah International University Lahore
Full name of responsible person
Maira Shahzad
Position
Student
Latest degree
Master
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
confidentiality of participants
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not 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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Consent form in its original format with no information about any participant study protocol -how the

intervention was given to both groups

When the data will become available and for how long

Data would be available after the completion of the research

To whom data/document is available

People working in an academic and clinical setting can have access to the above mentioned information/documents

Under which criteria data/document could be used

Data can be used for research paper

From where data/document is obtainable

Data can be asked at following email maairashahzad@gmail.com

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

One can ask for data at the given email address and it would be provided after knowing the general implications of sharing that particular data

Comments