Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparative effects of calisthenic exercises and isometric exercises on pain, balance and functional disability in diabetic patients with Knee Osteoarthritis

Protocol summary

Study aim

The aim of this study is to compare the effects of calisthenic exercises and isometric exercises on pain, balance and functional ability in diabetic patients with Knee Osteoarthritis

Design

Randomised, parallel group trial with blinded outcome assessment. Randomisation was centralised and computerised with concealed randomisation sequence carried out at an external site. That external site will be Research Randomizer software (https://www.randomizer.org/).

Settings and conduct

Study will be conducted at Allied Hospital Faisalabad and Outcome assessor, who was a serving physiotherapist in hospital, will be blinded

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Both male and female Age between 35 to 60 Inter-articular knee joint pathology Diagnosed osteoarthritis Grade 1 to 4 osteoarthritis Exclusion Criteria: History of lower extremity traumatic injury Any neurological deficits of the lower extremity History of any fracture or surgery on the lower extremity.

Intervention groups

Intervention group 1: will receive callisthenic exercises. Callisthenic exercises, also known as bodyweight exercises, are a form of physical activity that uses the own body's weight to provide resistance and build strength, flexibility, and endurance. These exercises can be performed without the need for equipment or weights, making them accessible and convenient for individuals of all fitness levels. Intervention group 2: will receive the hold relax technique. The "hold relax" technique, also known as proprioceptive neuromuscular facilitation (PNF) stretching, is a method used to increase flexibility and improve the range of motion in specific muscle groups. It involves a combination of stretching and muscle contraction to achieve greater gains in flexibility compared to traditional static stretching.

Main outcome variables

Knee joint pain; Knee joint range of motion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230306057633N2**
Registration date: **2023-05-15, 1402/02/25**
Registration timing: **retrospective**

Last update: **2023-05-15, 1402/02/25**
Update count: **0**

Registration date

2023-05-15, 1402/02/25

Registrant information

Name

Muhammad Talha Hassan Javed

Name of organization / entity

Riphah International University Faisalabad

Country

Pakistan

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-05, 1401/12/14

Expected recruitment end date

2023-05-05, 1402/02/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative effects of calisthenic exercises and isometric exercises on pain, balance and functional disability in diabetic patients with Knee Osteoarthritis

Public title
Effects of calisthenic exercises and isometric exercises on diabetic patients with knee osteoarthritis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Subject with inter-articular knee joint pathology Osteoarthritis diagnosed by an orthopedic surgeon Grade 1 and 2 knee osteoarthritis HbA1c should be 6.5 or more
Exclusion criteria:
Subject history of lower extremity traumatic injury Any Neurological deficit of lower extremity History of any lower limb surgery
Age
From **45 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, we employed a method of randomization known as simple randomization. The unit of randomization was the individual participant. To facilitate the randomization process, we utilized computer software specifically designed for this purpose. The software generated a random sequence of treatment assignments based on the predetermined block sizes and strata. The random sequence was built using established algorithms that ensure the generation of pseudorandom numbers. Pseudorandom numbers appear to be random but are generated using deterministic algorithms. To maintain allocation concealment, a crucial aspect of the randomization process, the treatment assignments were concealed from the researchers involved in participant enrollment and assignment. This was achieved by utilizing a centralized system or a secure database that stored the randomization sequence and assigned treatment codes or labels to participants in a manner that was not accessible to the researchers. This ensured that neither the researchers nor the participants knew the treatment assignment until after enrollment, reducing the potential for selection bias.
Blinding (investigator's opinion)
Single blinded
Blinding description
Developing a blinding protocol: The researchers will develop a detailed blinding protocol that outlines the procedures for blinding assessors, such as ensuring that they do not have access to information that could reveal the treatment allocation. Selecting assessors: The researchers will carefully select the assessors who will be responsible for evaluating the study's outcomes. These assessors will be trained to perform their evaluations without knowledge about the treatment allocation. Concealing treatment allocation: The researchers should conceal the treatment allocation from the assessors to prevent any biases arising from knowledge of the treatment. This can be achieved by using coded or unlabeled treatments, using a separate team to manage treatment allocation, or using blinding procedures such as sham treatments or placebo. Monitoring for unblinding: The researchers will monitor the study carefully to ensure that assessors are not inadvertently unblinded, such as through conversations with other study personnel or participants. Analyzing data: Once the study is complete, the researchers should analyze the data in a blinded manner to prevent any biases arising from knowledge of the treatment allocation.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research and Ethics Committee
Street address
Adjacent Fish Farm, Satayana Rd, Faisalabad, Punjab 44000
City
Faisalabad
Postal code
38000
Approval date
2023-02-15, 1401/11/26
Ethics committee reference number
REC-FSD-00321

Health conditions studied

1

Description of health condition studied
Knee Osteoarthitis
ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

Pain at Knee Joint

Timepoint

Pain will be measured at baseline, after 2 weeks and after 4 weeks

Method of measurement

Pain will be measured by Numeric Pain Rating Scale

Secondary outcomes

1

Description

Range of Motion at Knee Joint

Timepoint

Range of motion will be measured at baseline, after 2 weeks and after 4 weeks

Method of measurement

Range of motion will be measured by Goniometer

Intervention groups

1

Description

Intervention group 1: will receive Callisthenic Exercises. Calisthenics is a form of exercise that uses a person's body weight and requires little to no equipment. Here are many health benefits to calisthenics, and most people can start exercising right away. Participants will receive 3 sets of 15 repetitions with 5 seconds rests between the sets. This treatment session will continue for 3 sessions per week for 4 weeks. Hence participants will get total 12 sessions.

Category

Treatment - Other

2

Description

Intervention group 2: will receive Isometric Exercises. Isometric exercises are tightening (contractions) of a specific muscle or group of muscles. During isometric exercises, the muscle doesn't noticeably change length. Participants will receive 3 sets of 15 repetitions with 5 seconds rests between the sets. This treatment session will continue for 3 sessions per week for 4 weeks. Hence participants will get total 12 sessions.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Allied Hospital Faisalabad

Full name of responsible person

Sobia Nawaz

Street address

Dr. Tusi Rd, Faisalabad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Riphah International University Faisalabad

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Riphah International University Faisalabad

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 Faisalabad

Full name of responsible person
Muhammad Talha Hassan Javed

Position
Lecturer

Latest degree
Master

Other areas of specialty/work
Physiotherapy

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
Muhammad Talha Hassan Javed

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Person responsible for updating data

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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
Our decision not to share deidentified IPD in this study is based on several factors. First and foremost, ensuring the privacy and confidentiality of the study participants is of utmost importance to us. We take data protection and ethical considerations seriously, and we believe that releasing individual-level data could potentially compromise the anonymity and confidentiality of the participants. Furthermore, there may be legal and regulatory constraints that prevent us from sharing the deidentified IPD. These constraints could be related to data protection laws, patient consent requirements, or specific agreements with the participants or institutions involved in the study.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available