

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### Effects of Routine physical therapy with and without Hydrotherapy on Pain Intensity and Functional activity in knee Osteoarthritis Patients.

#### Protocol summary

##### Study aim

Aim of study was to know the effects of routine physical therapy with and without hydrotherapy on pain intensity and functional activity in knee osteoarthritis patients.

##### Design

A concealed, randomized, single blind clinical trial with parallel group design, consisted of 58 cases, enrolled between 26 December 2019 and 25 August 2020.

##### Settings and conduct

Data was collected from Department of Physical therapy university of Lahore teaching hospital Lahore Pakistan. Single blind study and assessor was blind in it.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Both males and females; 40 to 65 years of the age; Patients with osteoarthritis clinically diagnosed by orthopedic surgeon; Grade 2 and Grade 3 osteoarthritis patient; Have been diagnosed with at least unilateral degenerated OA. Non inclusion criteria: Hydrophobia; Traumatic OA; Recent surgery; Any cardiac disease; Fracture of lower limb; Knee joint replacement

##### Intervention groups

Control group: They received the regular designed physical therapy in which include TENS, HOT PACK, and Strengthening of knee joint. Intervention group : They received both routine physical therapy and hydrotherapy In routine PT, TENS, hot pack and strengthening of knee joint was given. In hydro three stages was included, warm-up (5 min), strengthening exercises (20 min), and a cool-down session (5 min). One set of 10 repetitions was increased to three sets of 10 repetitions for each exercises. Ankle weight was used around the ankle to provide additional resistance

##### Main outcome variables

Functional activity; pain score

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20200827048538N1**

Registration date: **2020-10-02, 1399/07/11**

Registration timing: **retrospective**

Last update: **2020-10-02, 1399/07/11**

Update count: **0**

##### Registration date

2020-10-02, 1399/07/11

#### Registrant information

##### Name

Sofia Tariq

##### Name of organization / entity

University of Lahore

##### Country

Pakistan

##### Phone

+92 42 36849457

##### Email address

sofiatariq32@gmail.com

#### Recruitment status

##### Recruitment complete

#### Funding source

##### Expected recruitment start date

2019-12-26, 1398/10/05

##### Expected recruitment end date

2020-05-26, 1399/03/06

##### Actual recruitment start date

2019-12-26, 1398/10/05

##### Actual recruitment end date

2020-08-25, 1399/06/04

##### Trial completion date

2020-08-25, 1399/06/04

#### Scientific title

Effects of Routine physical therapy with and without Hydrotherapy on Pain Intensity and Functional activity in knee Osteoarthritis Patients.

## Public title

Effects of Routine physical therapy with and without Hydrotherapy in knee Osteoarthritis.

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Both males and females 40 to 65 years of the age  
Patients with osteoarthritis (OA) clinically diagnosed by orthopedic surgeon Grade 2 and Grade 3 osteoarthritis  
Have been diagnosed with at least unilateral degenerated OA

### Exclusion criteria:

Hydrophobia Traumatic OA Recent surgery Any cardiac disease Neurological disorders Fracture of lower limb Knee joint replacement Skin diseases of lower limb Structural and functional disability Pathological and systematic disease Not to be used any walking support (such as walking stick or crutches)

## Age

From **40 years** old to **65 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Outcome assessor

## Sample size

Target sample size: **58**

Actual sample size reached: **48**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Randomization was done by using lottery method. Non-Probability Convenient Sampling was used to recruit the individuals for the study and then randomization was done by lottery method to divide the individuals into 2 groups. Sealed envelope will be used for allocation concealment.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

The assessor was blind and unaware of the treatment given into both control and study groups. Assessor was take 1st week and 4th week of followup total scoring.

## Placebo

Not used

## Assignment

Parallel

## Other design features

Null

## Secondary Ids

empty

## Ethics committees

## 1

### Ethics committee

#### Name of ethics committee

University Institute of Physical Therapy

#### Street address

House no.23; D/1 street; no.41 new colony  
Mujahidabad; Sahuwari

#### City

Lahore

#### Postal code

54000

### Approval date

2019-12-26, 1398/10/05

### Ethics committee reference number

IRB-UOL-FAHS/683/2020

## Health conditions studied

## 1

### Description of health condition studied

Grade 2 and Grade 3 Knee Osteoarthritis

### ICD-10 code

M17

### ICD-10 code description

Osteoarthritis of knee

## Primary outcomes

## 1

### Description

Functional activity

### Timepoint

Pre-assessment was taken at 1st week and final assessment was taken after 4 weeks.

### Method of measurement

Functional activity was measured by WOMAC Scale.

## 2

### Description

Pain intensity

### Timepoint

Pre-assessment was taken at 1st week and final assessment was taken after 4 weeks.

### Method of measurement

Pain assessment was measured by VAS Scale.

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Control Group: In regular physical therapy treatment include TENS, hot pack and isometrics of knee joint. Treatment period for almost 40 minutes. Total 12

sessions were given to patients, 3 times per week for consecutive 4 weeks.

### Category

Rehabilitation

## 2

### Description

Intervention group: In which both routine physical therapy and hydrotherapy treatment include . In hydrotherapy each session were include the following components: warm-up, lower limb ROM exercises and strengthening exercises. The program was including into three stages: warm-up (5 min), strengthening exercises (30 min), and a cool-down session (5 min). Warm-up exercises consisted of walking in the water and increasing velocity followed by stretching exercises of the anterior and posterior muscles of the lower limbs. After the warm-up session, participants will be performed lower limb strengthening exercises. In strengthening exercises Single leg squad, Semi squad, Side walk include. The cool-down session consisted of light walking. Participants will be instructed to perform the exercises on the high possible intensity. Ankle weight will be used around the ankle to provide additional resistance. Treatment period for almost one hour. Total 12 sessions were given to patients, 3 times per week for consecutive 4 weeks.

### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Physical therapy department, University Teaching Hospital, Lahore.

##### Full name of responsible person

Sofia Tariq

##### Street address

House no.23; D/1 street; no.41 new colony Mujahidabad; Sahuwari

##### City

Lahore

##### Postal code

54000

##### Phone

+92 42 36849457

##### Email

sofiatariq32@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

University of Lahore

##### Full name of responsible person

Sofia Tariq

#### Street address

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#### Grant name

#### Grant code / Reference number

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

No

#### Title of funding source

Null

#### 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

Other

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

University of Lahore

##### Full name of responsible person

Sofia tariq

##### Position

Student

##### Latest degree

Master

##### Other areas of specialty/work

Physiotherapy

##### Street address

House no.23; D/1 street; no.41 new colony Mujahidabad; Sahuwari

##### City

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

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

### Contact

**Name of organization / entity**  
University of Lahore

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**Email**  
sofiatariq32@gmail.com

## 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

there is no further decision and information decided yet.

### Study Protocol

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

### Statistical Analysis Plan

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

### Informed Consent Form

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

### Clinical Study Report

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

### Analytic Code

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

### Data Dictionary

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