# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## Comparison of the Effect Of Physiotherapy-Led Functional Exercise Regime vs. Conventional Therapy on Functional Outcomes After Total Hip Arthroplasty

### Protocol summary

**Study aim**
The aim of the study is to add in the evidence of physical therapy protocols after the surgical procedure of Total Hip Arthroplasty.

**Design**
Randomized controlled trial, single-centered, concealed, two arm parallel group of 82 patients, with blinded outcome assessment

**Settings and conduct**
Settings- Mayo Hospital Lahore (Orthopedics and Physiotherapy Department ) Blinded outcome assessor

**Participants/Inclusion and exclusion criteria**
Inclusion Criteria Age 30 to 60 years, Total hip arthroplasty, 1 to 16 weeks after THA, Able to understand instructions, Willing to come for all follow-ups, Exclusion Criteria Tumor / cancer, Total knee replacement, Revision arthroplasty surgery, Any underlying terminal disease, Suspicion of infection following joint replacement,

**Intervention groups**
Group A will receive Functional Exercise Protocol Group B will receive Conventional Exercises Protocol

**Main outcome variables**
Pain, stiffness, physical functioning, Health related quality of life,

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20220628055308N1**
Registration date: **2022-10-02, 1401/07/10**
Registration timing: **retrospective**

Last update: **2022-10-02, 1401/07/10**
Update count: **0**

**Registration date**
2022-10-02, 1401/07/10

**Registrant information**

**Name**
Dr. Samawiya Farooq
**Name of organization / entity**
King Edward Medical University, Lahore, Pakistan
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Pakistan
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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2022-04-28, 1401/02/08

**Expected recruitment end date**
2022-08-31, 1401/06/09

**Actual recruitment start date**
2022-04-28, 1401/02/08

**Actual recruitment end date**
2022-08-24, 1401/06/02

**Trial completion date**
2022-08-26, 1401/06/04

**Scientific title**
Comparison of the Effect Of Physiotherapy-Led Functional Exercise Regime vs. Conventional Therapy on Functional Outcomes After Total Hip Arthroplasty

**Public title**
Functional Outcomes After Total Hip Arthroplasty

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Age 30 to 60 years Total hip arthroplasty 1 to 16 weeks after THA Able to understand instructions Willing to come for all follow-ups
**Exclusion criteria:**
Tumor / cancer Total knee replacement Revision arthroplasty surgery Any underlying terminal disease Suspicion of infection following joint replacement

**Age**
From **30 years** old to **60 years** old

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **82**
Actual sample size reached: **82**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Randomized Control Trial Computer generated table of random numbers The sample was simply randomized into two equal groups (1:1) by MS Excel. The patients were individually assigned group as per the randomization table generated. The randomization sequence was built by using a "Rand" function in MS Excel on the sample of 82 patients with equal distribution of 41 sample among the two groups. The "Rand" function can be used to generate random numbers. It will return a random number between 0 and 1. The syntax for the RAND function in Microsoft Excel is: RAND( ). In 1st column of MS Excel spreadsheet, patient numbers were written i.e. 82 In the 2nd column, groups were written. In this study either it's a functional exercise/ group A or a conventional therapy group/ group B. The first 41 samples as functional exercise / group A and next 41 as conventional therapy group/ group B. In 3rd column, Randomization formula was added which is between 0-1 by Inserting a function called "Rand" in the first row of 3rd column. MS Excel has added a random number to the cell. The random number was then added in the entire column by dragging though the cells. Column 2 and column 3 were filtered in order to randomize column 2. After this column 3 was filtered in ascending order from the options of top row header to randomize it. All the content in column 2 were randomized. Likewise, all the patient numbers were randomized to either functional exercise/ group A or a conventional therapy group/ group B. The randomization table was generated by the other person and the group allotment of the participant was done by the other on the basis of concealed allocation. Allocation Concealment was carried out by sequentially numbered, opaque, sealed envelope (SNOSE) technique in which the randomization group were written on a paper and kept in an opaque sealed envelope. The envelope was labeled with a serial number. The investigator opens the sealed envelope once the patient has consented to participate and then assigns the treatment group accordingly.

**Blinding (investigator's opinion)**
Not blinded

**Blinding description**

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**
NA

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Institutional Review Board, KEMU, Lahore

**Street address**
Neelagumbad, Anarkali, Lahore Pakistan

**City**
Lahore

**Postal code**
54000

**Approval date**
2022-02-08, 1400/11/19

**Ethics committee reference number**
300/RC/KEMU/2022 (12-02-2022)

## Health conditions studied

### 1

**Description of health condition studied**
Total Hip Arthroplasty

**ICD-10 code**
Z96.64

**ICD-10 code description**
Presence of artificial hip joint

## Primary outcomes

### 1

**Description**
Pain

**Timepoint**
Before Intervention and 6 Weeks After Intervention

**Method of measurement**
VAS & WOMAC pain score

### 2

**Description**
Stiffness

**Timepoint**
Before Intervention and 6 Weeks After Intervention

**Method of measurement**
WOMAC Stiffness score

**3**

**Description**
Physical Functioning
**Timepoint**
Before Intervention and 6 Weeks After Intervention
**Method of measurement**
WOMAC Physical Functioning score

**4**

**Description**
Functional Outcomes
**Timepoint**
Before Intervention and 6 Weeks After Intervention
**Method of measurement**
WOMAC scores

**5**

**Description**
Health Related Quality of Life
**Timepoint**
Before Intervention and 6 Weeks After Intervention
**Method of measurement**
SF-12 Scores

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: Functional Exercise (Those 41 participants randomized to the intervention group will receive functional exercise under the supervision of the physiotherapist. Each session will be of approximately 35 minutes in length with 10 repetitions for a given exercises. Patients will attend the session twice weekly for 6 weeks, and will be given same exercises as a home exercise program. The functional exercise program in this study will be based on the following exercise plan: Sit to stand, Toe raises, Knee raises, Side and back leg raises, Partial knee bends, Single knee bends, One legged standing balance and advanced one legged standing balance, Pelvic raising and lowering.)
**Category**
Rehabilitation

**2**

**Description**
Control group: Conventional Therapy Group (Those randomized to the Group B will receive the conventional therapy protocol under the supervision of the physiotherapist. Each session will be of 35 minutes in length with 10 repetitions for a given exercises. Patients will attend the session twice weekly for 6 weeks and will be given same exercises as a home exercise plan. This will include the following exercise plan: Foot and ankle pumps, Static quadriceps contractions, Static gluteal contractions, Active hip flexion, Active hip extension, Active hip abduction, Hip external rotations and Hamstring Curls.)
**Category**
Rehabilitation

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Mayo Hospital Lahore, Pakistan
**Full name of responsible person**
Dr. Samawiya Farooq
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
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**Full name of responsible person**
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**Grant name**
No Grant Provided by the Institute
**Grant code / Reference number**
No Grant Provided by the Institute
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
King Edward Medical University, KEMU, Lahore, Pakistan
**Proportion provided by this source**
100
**Public or private sector**
Public
**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**
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King Edward Medical University, KEMU, Lahore, Pakistan
**Full name of responsible person**
Dr. Samawiya Farooq
**Position**
Post Graduate Resident- Trainee - M.Phil. Physiotherapy
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## Person responsible for scientific inquiries

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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**
"There is no further information"
**Study Protocol**
Yes - There is 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**
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**
Undecided - It is not yet known if there will be 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**
Comparison of the Effect Of Physiotherapy-Led Functional Exercise Regime vs. Conventional Therapy on Functional Outcomes After Total Hip Arthroplasty
**When the data will become available and for how long**
Data will be available after publication of the study.
**To whom data/document is available**
Data will be available after publication of the study to

Clinical researchers and physiotherapists.

**Under which criteria data/document could be used**

It can be used to further research on the topic.

**From where data/document is obtainable**

Contact with the corresponding author will be required.

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

Process can be done through email and can take few days to respond.

**Comments**

NA