

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effects of Sling Exercise Training on improve the Strength of Muscles , Range of Motion, and Functional Outcomes following Total knee Arthroplasty

Protocol summary

Study aim

The present study aims are intervention of a new active sling exercise therapy on enhancement of strength of muscles, and knee range of motion, and functional outcomes following total knee arthroplasty patients.

Design

Randomized, non-blinded clinical trial on 60 female knee arthroplasty patients with the age range of 50 to 70 years who are eligible to enter the study will be selected in two intervention and one control groups.

Settings and conduct

60 female patients undergoing total knee arthroplasty under the supervision of the same specialist doctor referring to Arian Physiotherapy Center located in Isfahan, will be selected and will be placed in one of the two intervention groups or the control group. At the beginning of the research, the WOMAC quality of life questionnaire, the strength of the examined muscles (Quadriceps and Hamstrings) and the range of motion of the knee joint will be measured. Then, the training protocols will be applied for eight weeks and after completion, the initial measurements will be made again.

Participants/Inclusion and exclusion criteria

entry conditions: Having a female gender with an age range of 50-70 years, performing a total knee arthroplasty in the last 2 months by specific doctor; Conditions of non-entry: suffering from acute cardiovascular problems or a specific disease that prevents sports activities.

Intervention groups

The first intervention group performed 3 sessions per week for 8 weeks, performed sling exercises therapy after the physiotherapy, the second intervention group performed the rehabilitation exercise protocol for total knee arthroplasty after the physiotherapy, and the control group without exercise intervention after the physiotherapy .

Main outcome variables

Strength of Quadriceps, Hamstrings muscles, Knee Range of motion(Flexion and Extension), Functional outcomes.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221226056934N1**

Registration date: **2023-02-25, 1401/12/06**

Registration timing: **registered_while_recruiting**

Last update: **2023-02-25, 1401/12/06**

Update count: **0**

Registration date

2023-02-25, 1401/12/06

Registrant information

Name

Nooshin Rajaeian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 4532 2194

Email address

noushin.rajaeian@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-24, 1401/12/05

Expected recruitment end date

2023-04-04, 1402/01/15

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effects of Sling Exercise Training on improve the Strength of Muscles , Range of Motion, and Functional Outcomes following Total knee Arthroplasty

Public title
Effects of Sling Exercise Training on improve the Strength of Muscles , Range of Motion, and Functional Outcomes following Total knee Arthroplasty

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Total Knee Arthroplasty since 2 months
Exclusion criteria:

Age
From **50 years** old to **70 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple Random Sampling: The people of the society will be numbered first and after the lottery will be randomly placed in three groups (two intervention and one control).

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Sport Science Research Institute Of Iran
Street address
No.3, 5th St., Mir Emad St., Motahari Ave
City

Tehran
Province
Tehran
Postal code
1587958711
Approval date
2023-02-19, 1401/11/30
Ethics committee reference number
IR.SSRC.REC.1401.110

Health conditions studied

1

Description of health condition studied
Rehabilitation of Total Knee Arthroplasty
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Strength of Quadriceps and Hamstring muscles
Timepoint
At the beginning of the study before the intervention and after 8 weeks
Method of measurement
J-Tech American dynamometer

2

Description
Knee joint flexion and extension range of motion
Timepoint
At the beginning of the study before the intervention and after 8 weeks
Method of measurement
Goniometer

3

Description
Knee Functionals Outcomes
Timepoint
At the beginning of the study before the intervention and after 8 weeks
Method of measurement
WOMAC quality of life questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Three sessions a week for 8 weeks of Sling exercises

Category

Rehabilitation

2**Description**

Intervention group 2: Rehabilitation protocol after Total knee Arthroplasty

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Arian Physiotherapy and Rehabilitation Clinic

Full name of responsible person

Mojtaba Ghazi Isfahani

Street address

No. 35., 1st West St., Parvin Etesami Blvd

City

Shahinshahr

Province

Isfahan

Postal code

8314816531

Phone

+98 31 4527 8156

Email

noushin.rajaeian@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Majid Toghiani

Street address

University Blvd., Arghwanieh St., Jey Ave.

City

Khorasgan

Province

Isfahan

Postal code

8155139998

Phone

+98 31 3535 4001

Email

info@khuisf.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Islamic Azad University

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**

Islamic Azad University

Full name of responsible person

Nooshin Rajaeian

Position

دانشجو

Latest degree

Master

Other areas of specialty/work

Sport science(sport injury and corrective exercise therapy)

Street address

No. 46, East 13th Ave., Atar Blvd

City

Shahinshahr

Province

Isfahan

Postal code

8318615946

Phone

+98 31 4532 2194

Fax**Email**

noushin.rajaeian@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Nooshin Rajaeian

Position

دانشجو

Latest degree

Master

Other areas of specialty/work

Sport science(sport injury and corrective exercise therapy)

Street address

No. 46, East 13th Ave., Atar Blvd

City

Shahinshahr

Province

Isfahan

Postal code

8318615946

Phone

+98 31 4532 2194

Fax**Email**

noushin.rajaeian@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Nooshin Rajaeian

Position

دانشجو

Latest degree

Master

Other areas of specialty/work

Sport science(sport injury and corrective exercise therapy)

Street address

No. 46, East 13th Ave., Atar Blvd

City

Shahinshahr

Province

Isfahan

Postal code

8318615946

Phone

+98 31 4532 2194

Fax**Email**

noushin.rajaeian@gmail.com

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All potential data are released after de-identification of individuals in the form of information on main outcomes.

When the data will become available and for how long

The access period starts 6 months after the results are published.

To whom data/document is available

All researchers, lecturers and students of medical sciences can receive the printed article from the relevant journal

Under which criteria data/document could be used

Non-identifiable data will be made available to health science researchers for study.

From where data/document is obtainable

Send email to Noushin Rajaeian .
noushin.rajaeian@gmail.com

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

After sending the documents by the applicant researcher via email; Data will be sent around two weeks later.

Comments