

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effectiveness of Routine Physical Therapy with and without Core Stability Exercises in Patients with Rotator Cuff Tendinopathy.

Protocol summary

Study aim

The aim of the study is to describe the importance of core stability's association with efficient mobility of extremities needs to be included in Rotator Cuff tendinopathy rehabilitation, along with conventional measures.

Design

Randomized controlled, single blinded clinical trial. The treatment have either superior, parallel effects to the control group. Single centered

Settings and conduct

Water and Power Development Authority Teaching Hospital Complex, physical therapy department. Patients who fulfil the above mentioned criteria were identified by individual physiotherapist and then enrolled in particular study group. Informed written consent was taken by the patients and was randomly allocated by using the lottery method to two groups. The total number of sessions was 12 and duration of the treatment was 4 weeks. The study was single blinded. The assessor was unaware of the treatment given to both groups.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Diagnosed rotator cuff tendinopathy patients. Both genders were included. Age: 25-50 years. Exclusion Criteria: Any deformity of upper, lower extremity and spine. Any surgery of shoulder and spine. Tumor. Trauma and fracture. Cervical Radiculopathy.

Intervention groups

Experimental group: therapeutic ultrasound (Frequency: 1.1MHz, Intensity: 1.5 W/cm²), stretching and strengthening exercise of cervical and shoulder and Core Stability exercises. Duration: 45-60 minutes, 3 times a week, 3 sets, 10-15 repetitions with 10 seconds hold. Control group: therapeutic ultrasound (Frequency: 1.1MHz, Intensity: 1.5 W/cm²), stretching and strengthening exercise of cervical and shoulder. Duration: 45-60 minutes, 3 times a week, 3 sets, 10-15 repetitions with 10 seconds hold.

Main outcome variables

Visual analogue scale (VAS) Comparative pain scale chart. Shoulder pain and disability index (SPADI) Range of motion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210118050074N1**

Registration date: **2022-01-11, 1400/10/21**

Registration timing: **retrospective**

Last update: **2022-01-11, 1400/10/21**

Update count: **0**

Registration date

2022-01-11, 1400/10/21

Registrant information

Name

Mahrukh Asghar

Name of organization / entity

University of the Lahore

Country

Pakistan

Phone

+92 42 35968450

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mahrukhasghar@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-10-30, 1399/08/09

Actual recruitment start date

2020-02-05, 1398/11/16

Actual recruitment end date

2020-12-30, 1399/10/10

Trial completion date

2021-03-27, 1400/01/07

Scientific title

Effectiveness of Routine Physical Therapy with and without Core Stability Exercises in Patients with Rotator Cuff Tendinopathy.

Public title

Core Stability exercises for Rotator cuff Tendinopathy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosed patients with rotator cuff tendinopathy

Exclusion criteria:

Any deformity of upper extremity, lower extremity and spine Any surgery of shoulder and spine Tumor Any traumatic injury and fracture Cervical radiculopathy

Age

From **25 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **54**

Actual sample size reached: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple Randomization of individuals. All the individuals were allocated in two groups, odd numbers were given to group A (Experimental) and even numbers were given to group B (Control). Sealed enveloped method was used for randomization by using Sobolsoft software. Allocation concealment was carried out by Sequentially numbered, opaque, sealed envelope (SNOSE) technique.

Blinding (investigator's opinion)

Single blinded

Blinding description

The assessor was blinded by simply not informing. The assessor after assessment handed over the envelop to the patient and then patient handed over the envelop to the therapist.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

University of Lahore, Institutional review board

Street address

1 KM Defense road, Off bhobatian chowk, Lahore

City

Lahore

Postal code

54000

Approval date

2020-03-06, 1398/12/16

Ethics committee reference number

IRB-UOL-FAHS/718-XX/2020

Health conditions studied**1****Description of health condition studied**

Rotator cuff tendinopathy

ICD-10 code

M75.102

ICD-10 code description

Unspecified rotator cuff tear or rupture of left shoulder, not specified as traumatic

Primary outcomes**1****Description**

Pain

Timepoint

Before intervention, 4 weeks, at 6th session and 12th session

Method of measurement

Visual analogue scale

2**Description**

Range of Motion

Timepoint

Before intervention, 4 weeks, at 6th session and 12th session

Method of measurement

Universal goniometer

3**Description**

Functional status

Timepoint

Before intervention, 4 weeks, at 6th session and 12th session

Method of measurement

Shoulder pain and disability index (SPADI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group received routine physical therapy and core stability exercises. This includes patient education, therapeutic ultrasound, stretching and strengthening exercises. Shoulder exercises; Range of Motion, pendulum exercises, stretching exercises of shoulder and cervical, core stability exercises. Duration: 45 minutes approx., Frequency: 3 times a week, Sets: 3sets, Repetition: 10-15 repetitions, Hold: 10 sec.

Category

Rehabilitation

2

Description

Control group received only routine physical therapy; includes patient education, therapeutic ultrasound, stretching and strengthening exercises. Shoulder exercises; Range of Motion, pendulum exercises, stretching exercises of shoulder and cervical. Duration: 45 minutes approximately. Frequency: 3 times a week. Sets: 3 sets. Repetition: 10-15 repetitions. Hold: 10 second.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Water and Power Development Authority Teaching Hospital Complex

Full name of responsible person

Dr. Abid Javed Minhas

Street address

210- Ferozepur road Lahore.

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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

Grant code / Reference number

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

Yes

Title of funding source

University of Lahore

Proportion provided by this source

20

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

Mahrukh Asghar

Position

Student

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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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 PlanUndecided - It is not yet known if there will be a plan to
make this available**Informed Consent Form**

Yes - There is a plan to make this available

Clinical Study ReportUndecided - It is not yet known if there will be a plan to
make this available**Analytic Code**

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Abstract.

When the data will become available and for how long

After publication the data will be available for 5 years.

To whom data/document is available

Public and physical therapists.

Under which criteria data/document could be usedOnly physical therapists can use the data for research
purpose.**From where data/document is obtainable**

From personal email.

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

Steps: 1. provide study plan 2. CV 3. Request letter

Comments