Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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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

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210- Ferozepur road Lahore.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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 Plan
Undecided - 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 Report
Undecided - 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 used
Only 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