

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effects of TMJ exercises on pain, range of motion and functional disability in patient with non-specific neck pain.

Protocol summary

Study aim

To compare the effects of Effects of TMJ exercises on pain, range of motion and functional disability in patient with non-specific neck pain.

Design

Parallel group, single-blinded, randomized controlled trial

Settings and conduct

OPD Physiotherapy department university of Lahore, Lahore

Participants/Inclusion and exclusion criteria

Inclusion Criteria:- age of 18-55 years old, and with primary complaints of NSNP (symptoms lasting for at least 3 months), one of the four signs of TMD (joint sounds, deviation during mouth opening, muscle pain at a minimum of two tender points in the temporalis or masseter muscles and pain during mouth opening), Both male and female patients, Exclusion Criteria:- acute muscle trauma, received physiotherapy during the previous 3 months, unilateral and bilateral upper extremity symptoms, any neurological disorders, Musculoskeletal systemic disease, serious spinal pathology.

Intervention groups

All person who came to physiotherapy department OPD, university of Lahore was consider and assess for NSNP. 50 patients were randomly apportioned into 2 groups, 25 patients in each group. Gathering A patient were dealt with routine physiotherapy while Group B patients were treated with jaw activities and routine physiotherapy. Randomization of patients into groups were finished by mean of lottery strategy. Plan of the investigation was single blinded RCT. In which patients was kept blind. Furthermore, in this investigation patients were kept visor.

Main outcome variables

- Pain, ROM, Functional Activity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200611047734N3**

Registration date: **2021-09-19, 1400/06/28**

Registration timing: **retrospective**

Last update: **2021-09-19, 1400/06/28**

Update count: **0**

Registration date

2021-09-19, 1400/06/28

Registrant information

Name

AYESHA RAZZAQ

Name of organization / entity

King Edward Medical University, Lahore

Country

Pakistan

Phone

+92 61 6521475

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-02, 1398/10/12

Expected recruitment end date

2020-10-02, 1399/07/11

Actual recruitment start date

2020-03-07, 1398/12/17

Actual recruitment end date

2020-12-07, 1399/09/17

Trial completion date

2020-12-07, 1399/09/17

Scientific title

Effects of TMJ exercises on pain, range of motion and functional disability in patient with non-specific neck pain.

Public title

Effects of TMJ exercises on pain, range of motion and functional disability in patient with non-specific neck pain.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of 18-55 years old With primary complaints of NSNP (symptoms lasting for at least 3 months) One of the four signs of TMD (joint sounds, deviation during mouth opening, muscle pain at a minimum of two tender points in the temporalis or masseter muscles and pain during mouth opening). Both male and female patients The severity of pain should be adequate (on a numerical pain rating scale it should be higher than 2 out of 10) for approving a clinically beneficial effect to be exhibited

Exclusion criteria:

Acute muscle trauma, Received physiotherapy during the previous 3 months Unilateral and bilateral upper extremity symptoms Any neurological disorders. Musculoskeletal systemic disease Serious spinal pathology Thoracic outlet syndrome Cervical rib Cervicogenic headache and vertigo. The previous history of whiplash trauma, prior to 6 weeks of inspection .Patients with h/o fractures of cervical or thoracic spine Any former h/o cervico-thoracic surgery

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **50**

More than 1 sample in each individual

Number of samples in each individual: **2**

25 patients will be in each group, estimated by using 5% level of significance, 90% power of test

Actual sample size reached: **50**

More than 1 sample in each individual

Actual sample size in each individual: **2**

25 patients will be in each group, estimated by using 5% level of significance, 90% power of test

Randomization (investigator's opinion)

Randomized

Randomization description

All the participants who will come to the physiotherapy department will be considered and screen for nonspecific neck pain. 50 patients will be allotted in two groups i.e.; group A(routine physiotherapy) and group B(TMJ exercise+ routine physiotherapy) via lottery method, 25 in each group. patients with having lottery number with group A treated with just baseline treatment of

physiotherapy, and patient having lottery method with Group B managed with baseline treatment and also receive a additional technique that was TMJ exercise.

Blinding (investigator's opinion)

Single blinded

Blinding description

it will be a single-blind study in which participant/ patients will be kept blind for treatment technique. 2 different technique will be provided to patients. and they will blind about that which technique will be given to which patients.

Placebo

Not used

Assignment

Parallel

Other design features

Parallel groups, single blinded, single setting

Secondary Ids

empty

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

Institutional Review Board

Street address

Raiwind road lahore

City

LAHORE

Postal code

55150

Approval date

2020-03-06, 1398/12/16

Ethics committee reference number

IRB UOL FAHS/734 111/2020

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

nonspecific neck pain

ICD-10 code

M43.02

ICD-10 code description

Spondylolysis, cervical region

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

Pain

Timepoint

Baseline and after 4th week

Method of measurement

Numeriac pain rating scale

2

Description

Range of motion

Timepoint

Baseline and after 4th week

Method of measurement

Goniometer

3

Description

Functional activity

Timepoint

Baseline and after 4th week

Method of measurement

Neck Functional Disability index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Group A (Routine Physiotherapy): - Hot pack + TENS+ neck isometrics exercises. Dosage: - o Hot pack for 20 minutes o TENS= 100Hz, 50 μ s pulse, 20 minutes.o Isometrics Neck exercise = 10 times repetition .

Category

Treatment - Devices

2

Description

Intervention group: Group B (Jaw Exercises + Routine Physiotherapy): - Hot pack + TENS+ jaw exercises + neck isometrics exercises. Dosage: - o Hot pack for 20 minutes o TENS= 100Hz, 50 μ s pulse, 20 minutes.o Jaw exercises: - 10 times repetitiono Isometrics Neck exercise = 10 times repetition .

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

OPD Physiotherapy department university of Lahore, Lahore.

Full name of responsible person

Muhammad Riwan

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Raiwind Road

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rizwanakhter66@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

university of Lahore, Lahore

Full name of responsible person

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Grant name

Muhammad Rizwan

Grant code / Reference number

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

Yes

Title of funding source

university of Lahore, 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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

university of Lahore, Lahore

Full name of responsible person

Muhammad Rizwan

Position

lecturer

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

Yes - There is a plan to make this available

Data Dictionary

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

Title and more details about the data/document

Effects of Temporomandibular joint exercises on pain, range of motion and functional disability in patient with non-specific neck pain

When the data will become available and for how long

study is completed and become available after its publication

To whom data/document is available

person in academic institute. Patient data will not be shown

Under which criteria data/document could be used

under the usage with terms in which journal is accessed /processed for publication it could be used in request.

From where data/document is obtainable

+923367595206 from the University office and Responsible supervisor and from journal we will process in future

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

can be on call or mail It will be only used in confidential way for improving research and benefit of humanity

Comments

data can be provided on request