

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effectiveness of temporomandibular joint mobilization with & without neck strengthening exercises on patients with anterior disc displacement with reduction of temporomandibular joint

Protocol summary

Study aim

To evaluate the effectiveness of neck strengthening exercises on pain, Jaw mobility and clicking/popping sound of the disc displacement with reduction of temporomandibular joint in addition to routine physical therapy.

Design

Randomized controlled Clinical trial. A Superiority clinical trial. The treatments of interest have either superior effects or similar effects to the control group

Settings and conduct

study setting: University of Lahore Teaching Hospital, University of Lahore. Study Duration: 9 Months after the approval of synopsis. Non-probability; Purposive sampling technique. It is a Single blinded study. The assessor and the data analyzer were blind.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 18-50 years Male & Female Temporomandibular joint Pain plus disc displacement with reduction. 4. Diagnosed Patients Exclusion Criteria: 1. Recent tumor, fracture or trauma in recent medical history 2. Any Systemic/Rheumatic disease. 3. Degenerative changes seen 4. Surgical History of cervical spine Or Temporomandibular joint.

Intervention groups

For Control Group: Manual Mobilization of Temporomandibular joint Soft Tissue Release of Masticatory muscles Therapeutic Exercises of Temporomandibular joint including Protrusion and Lateral shifting will be given for home plan. For Treatment Group. All of the above-mentioned treatment protocol with additionally strengthening exercises of deep neck flexors muscles including: Longus Capitus and Longus Colli muscles was given as a home plan thrice a day with 10 repetitions and 10 second hold

Main outcome variables

Pain intensity, Jaw Mobility, clicking sound

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200823048495N2**

Registration date: **2021-02-12, 1399/11/24**

Registration timing: **retrospective**

Last update: **2021-02-12, 1399/11/24**

Update count: **0**

Registration date

2021-02-12, 1399/11/24

Registrant information

Name

Umber Nawaz

Name of organization / entity

Knowledge Research and Innovation Center

Country

Pakistan

Phone

+92 42 35440889

Email address

umber@kric.edu.pk

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-06, 1398/12/16

Expected recruitment end date

2020-12-04, 1399/09/14

Actual recruitment start date

2019-12-04, 1398/09/13

Actual recruitment end date

2020-10-04, 1399/07/13

Trial completion date

2020-10-04, 1399/07/13

Scientific title

Effectiveness of temporomandibular joint mobilization with & without neck strengthening exercises on patients with anterior disc displacement with reduction of temporomandibular joint

Public title

Neck strengthening exercises in anterior disc displacement with reduction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Temporomandibular Joint Pain plus disc displacement with reduction patient with a medical referral of Temporomandibular disorder by dentists/ maxillofacial surgeon Symptoms for more than 1 month, at the time that the first treatment would be given

Exclusion criteria:

Recent tumor fracture or trauma in recent medical history Any Systemic/Rheumatic disease Degenerative changes seen Surgical History of cervical spine Or Temporomandibular joint

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **53**

Actual sample size reached: **53**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple Randomization Sealed Envelops Odd number to the control group and Even number to the treatment group

Blinding (investigator's opinion)

Single blinded

Blinding description

The outcome assessor have been blinded by simply not informing him of the group allocation of the participants. After Assessment the assessor was asked to handover the sealed envelope with a number written on the envelope. The Assessor was not aware of the random numbers and group allocation. Every odd number was then allocated to control group by the therapist and every even number was allocated to intervention group by the therapist.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

World Health Organization Universal Trial Registry

Secondary trial Id

U1111-1262-8127

Registration date

2020-12-16, 1399/09/26

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic's committee of The University of Lahore, Faculty of Allied health Science,

Street address

1 KM- Raiwind Road, Bhoptian Chowk, Main Campus, Lahore, Pakistan

City

Lahore

Postal code

54700

Approval date

2020-03-06, 1398/12/16

Ethics committee reference number

IRB-UOL-FAHS/718-XVI/2020

Health conditions studied

1

Description of health condition studied

Anterior disc displacement with reduction of Temporomandibular Joint Disorder

ICD-10 code

M26.63

ICD-10 code description

Articular disc disorder of temporomandibular joint

Primary outcomes

1

Description

Pain

Timepoint

before intervention and 4 weeks after intervention

Method of measurement

Numeric Pain Scale

2

Description

Jaw Mobility

Timepoint

before intervention and 4 weeks after intervention

Method of measurement

Measuring Scale

3

Description

Clicking Sounds

Timepoint

before intervention and 4 weeks after intervention

Method of measurement

Stethoscope

Secondary outcomes

1

Description

Helkimo Index

Timepoint

before intervention and 4 weeks after intervention

Method of measurement

Helkimo Index

Intervention groups

1

Description

Intervention group: Manual Mobilization of temporomandibular joint will be applied in all sessions with 3-5 repetitions in 1 set. 3 sets were applied. Once a day. Soft Tissue Release of Masticatory muscles including: Masseter, lateral/ medial pterygoid & Temporalis for 2 min on each muscle. Once a day. Therapeutic Exercises of temporomandibular joint including Protrusion and Lateral shifting will be given for home plan. 2 times a day with 5-6 repetitions and 10 second hold with additionally strengthening exercises of deep neck flexors muscles including: Longus Capitus and Longus Colli muscles was given as a home plan thrice a day with 10 repetitions and 10 second hold.

Category

Rehabilitation

2

Description

Control group: Manual Mobilization of temporomandibular joint will be applied in all sessions with 3-5 repetitions in 1 set. 3 sets were applied. Once a day. Soft Tissue Release of Masticatory muscles including: Masseter, lateral/ medial pterygoid & Temporalis for 2 min on each muscle. Once a day. Therapeutic Exercises of temporomandibular joint including Protrusion and Lateral shifting will be given for home plan. 2 times a day with 5-6 repetitions and 10 second hold.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

The University of Lahore, Faculty of Allied health Science,

Full name of responsible person

Umber Nawaz

Street address

1 KM- Raiwind Road, Bhoptian Chowk, Main Campus, Lahore, Pakistan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Lahore

Full name of responsible person

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Web page address

Grant name

Self

Grant code / Reference number

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

No

Title of funding source

Self

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

The University of Lahore

Full name of responsible person

Umber Nawaz

Position

Lecturer

Latest degree

Master

Other areas of specialty/work

musculoskeletal Rehabilitation

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Person responsible for scientific inquiries

Contact

Name of organization / entity

The University of Lahore

Full name of responsible person

Umber Nawaz

Position

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Latest degree

Master

Other areas of specialty/work

Musculoskeletal Manual Rehabilitation

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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

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

IPD collected for the primary outcome measure

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

Data will be available to all the researchers, academic institutions and common public.

Under which criteria data/document could be used

Data will be accessible to the researchers on request at umber@kric.edu.pk or umber.nawaz@uipt.uol.edu.pk

From where data/document is obtainable

communication and clear contact information such as email addresses mentioned previously along with cover letter and resume and purpose of the data need.

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

Requested email to the following addresses:
umber@kric.edu.pk, umber.nawaz@uipt.uol.edu.pk

Comments

