# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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**
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The University of Lahore
**Full name of responsible person**
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umber.nawaz@uipt.uol.edu.pk
**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

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## Person responsible for updating data

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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**