

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

IMMEDIATE AND PROLONGED EFFECTS OF TEMPOROMANDIBULAR JOINT MOBILIZATION ON PAIN, RANGE OF MOTION AND FUNCTIONAL DISABILITY IN HYPOMOBILE TEMPOROMANDIBULAR JOINT PATIENTS; A RANDOMIZED CONTROLLED TRIAL

Protocol summary

Study aim

To compare the immediate and prolonged effects of temporomandibular joint mobilization on pain, range of motion and functional disability in hypomobile temporomandibular joint patients

Design

Single blind, Randomized controlled trial, superiority analysis of the treatment group

Settings and conduct

University Institute of Physical Therapy, The University of Lahore Teaching Hospital.

Participants/Inclusion and exclusion criteria

Inclusion Criteria • Aged between 20 and 35 years • Pain in the region of the Temporomandibular joint and masticatory muscles • Associated muscles and limited mandibular movement for at least six months • Complete dentition to provide stable and repeatable base points for jaw measurements. • Diagnosed by an experienced clinician as suffering from Temporomandibular disorders • Decreased mandibular opening
Exclusion Criteria • History of severe head trauma or surgery • Known cervical pathology • Taking any medication except for occasional analgesics.

Intervention groups

- Temporomandibular Joint Mobilization Group (Group I)
- Control Group (Group II)

Main outcome variables

- Pain • Range of Motion • Functional Disability

General information

Reason for update

Acronym

TMJ

IRCT registration information

IRCT registration number: **IRCT20210913052456N1**

Registration date: **2022-02-02, 1400/11/13**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-02, 1400/11/13**

Update count: **0**

Registration date

2022-02-02, 1400/11/13

Registrant information

Name

Naveeda Ashraf

Name of organization / entity

University of Lahore

Country

Pakistan

Phone

+92 42 35440889

Email address

naveedaashraf123@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-25, 1400/08/03

Expected recruitment end date

2022-06-25, 1401/04/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

IMMEDIATE AND PROLONGED EFFECTS OF TEMPOROMANDIBULAR JOINT MOBILIZATION ON PAIN,

RANGE OF MOTION AND FUNCTIONAL DISABILITY IN HYPOMOBILE TEMPOROMANDIBULAR JOINT PATIENTS; A RANDOMIZED CONTROLLED TRIAL

Public title

Immediate and prolong effects of manual therapy on Jaw

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

• Pain in the region of the Temporomandibular joints and masticatory • Associated muscles and limited mandibular movement for at least six months •

Complete dentition to provide stable and repeatable base points for jaw measurements. • Diagnosed by an experienced clinician as suffering from Temporomandibular disorders • Decreased mandibular opening

Exclusion criteria:

• History of severe head trauma or surgery • Known cervical pathology • Taking any medication except for occasional analgesics.

Age

From **20 years** old to **35 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **70**

More than 1 sample in each individual

Number of samples in each individual: **35**

Purposive sampling

Randomization (investigator's opinion)

Randomized

Randomization description

Simple Randomization with Sealed Envelops will be given by the assessor after pre-treatment assessment Odd number will be given to the control group and Even numbers will be given 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 will be 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 will be then allocated to control group by the therapist and every even number will be allocated to intervention group by the therapist.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The University of Lahore, Faculty of Allied health Science, Institutional Review Board

Street address

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

City

Lahore

Postal code

54700

Approval date

2020-10-27, 1399/08/06

Ethics committee reference number

IRB-UOL-FAHS/761/2020

Health conditions studied

1

Description of health condition studied

temporomandibular joint disorder

ICD-10 code

M26.6

ICD-10 code description

Temporomandibular joint disorders

Primary outcomes

1

Description

- Pain

Timepoint

4 weeks

Method of measurement

Visual Analogue Scale

2

Description

- Range of Motion

Timepoint

4 weeks

Method of measurement

Goniometer, Vernier Calliper

3

Description

Functional disability

Timepoint

4 weeks

Method of measurement

Jaw disability index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in this group will get on spot session of 30 minutes session of manual therapy. Mulligan technique will be applied

Category

Rehabilitation

2

Description

Control group: Transcutaneous Electrical Neuromuscular Stimulation, Hot pack and soft tissue technique will be applied to the patients

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

University institute of physical therapy, The University of Lahore,

Full name of responsible person

Dr. Ashfaq Ahmad

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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Grant name

Self Support

Grant code / Reference number

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

Yes

Title of funding source

The University of Lahore

Proportion provided by this source

50

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

The University of Lahore

Full name of responsible person

Naveeda Ashraf

Position

Lecturer

Latest degree

Master

Other areas of specialty/work

Rehabilitation management

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Person responsible for scientific inquiries

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Full name of responsible person

Umber Nawaz

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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

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

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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

To researcher

Under which criteria data/document could be used

Data will be accessible to the researchers on request at
naveeda.ashraf@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:
naveeda.ashraf@uipt.uol.edu.pk
umber.nawaz@uipt.uol.edu.pk

Comments