Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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+92 42 35440889

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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
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Sponsors / Funding sources

1

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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
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Full name of responsible person
Naveeda Ashraf
Position
Lecturer
Latest degree
Master
Other areas of specialty/work
Rehabilitation management
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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
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

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