

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effects of routine treatment and manual therapy on pain, and range of motion in patients with temporomandibular disorders

#### Protocol summary

##### Study aim

The effects of routine treatment and manual therapy in patients with temporomandibular disorders

##### Design

This study included two groups: control group and intervention group. study design: randomized control trial with control group, parallel group. The patients and outcome assessor will be blind

##### Settings and conduct

Place of study: Iran University of Medical Sciences, School of rehabilitation, Ultrasonography laboratory  
Method: This study included two groups: control group and intervention group. Control group: The control group will receive the routine physiotherapy including gentle massage over the masseter muscle, ultrasound 1 MHz and TENS. The intervention group will receive the routine physiotherapy AND manual therapy of temporomandibular joint and upper cervical .

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-unilateral or bilateral TMD according to the DC/TMD 2-pain more than 3 based on visual analog scale Exclusion criteria: 1-a traumatic injury that caused the symptoms in the temporomandibular joint and the orofacial region during the last three months 2-history of the orofacial surgery during the last 6 months 3-neurological and systemic diseases such as rheumatoid arthritis; Parkinson; multiple sclerosis, positional vertigo, pregnancy, and severe deformity in the jaw or face region

##### Intervention groups

Control group: The control group will receive the routine physiotherapy such as massage, therapeutic ultrasound 1MHZ and TENS for eight weeks. Intervention group: The intervention group will receive the routine physiotherapy and manual therapy of TMJ and cervical spine. The patients in both groups will receive routine physiotherapy 10 sessions during eight weeks.

##### Main outcome variables

pain; maximum mouth opening, cervical flexion and

extension range of motions,

#### General information

##### Reason for update

Lack of time in coronary conditions

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190621043964N1**

Registration date: **2019-06-29, 1398/04/08**

Registration timing: **prospective**

Last update: **2021-07-19, 1400/04/28**

Update count: **1**

##### Registration date

2019-06-29, 1398/04/08

##### Registrant information

##### Name

Khaled Rezaie

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2222 8051

##### Email address

rezaie.kh@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-11-01, 1398/08/10

##### Expected recruitment end date

2021-02-01, 1399/11/13

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

The effects of routine treatment and manual therapy on pain, and range of motion in patients with temporomandibular disorders

**Public title**

The effects of routine treatment and manual therapy in people with temporomandibular disorder

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Individuals with unilateral or bilateral TMD according to the DC/TMD pain more than 3 based on visual analog scale

**Exclusion criteria:**

traumatic injury that caused the symptoms in the temporomandibular joint and the orofacial region during the last three months history of the orofacial surgery during the last 6 months neurological and systemic diseases such as rheumatoid arthritis; Parkinson; multiple sclerosis, positional vertigo, pregnancy, and severe deformity in the jaw or face region

**Age**

From **20 years** old to **50 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization method: Block balanced randomization design, block size:4, ratio 1:1 Randomization tool: Random allocation will be performed using the website of [www.randomization.com](http://www.randomization.com).

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee**

**Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

**Street address**

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۴۹۶۱۴۵۳۵

**Approval date**

2018-10-28, 1397/08/06

**Ethics committee reference number**

Ir.lums.Rec.1397.1054

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

Temporomandibular dysfunction

**ICD-10 code**

M26.6

**ICD-10 code description**

Temporomandibular joint disorders

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

pain

**Timepoint**

At the baseline, after the end of the treatment, and after a one-month follow-up period

**Method of measurement**

Visual analog scale

**Secondary outcomes****1****Description**

Maximum mouth opening

**Timepoint**

At the baseline, after the end of the treatment, and after a one-month follow-up period

**Method of measurement**

caliper

**2****Description**

Cervical flexion and extension ROM

**Timepoint**

At the baseline, after the end of the treatment, and after a one-month follow-up period

**Method of measurement**

Goniometer

## Intervention groups

### 1

#### Description

Control group: The control group will receive the routine physiotherapy such as gentle massage over the masseter muscles , therapeutic ultrasound 1MHZ and TENS for ten sessions during 8 weeks.

#### Category

Rehabilitation

### 2

#### Description

Intervention group: The intervention group will receive the routine physiotherapy such as gentle massage over the masseter muscles , therapeutic ultrasound 1MHZ and TENS and manual therapy of the TMJ and upper cervical spine. This group will receive the interventions for ten sessions during 8 weeks.

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shariati hospital

##### Full name of responsible person

Khaled Rezaie

##### Street address

Shariati Shariati Hospital, Jalal-e-Al-e-Ahmad Hwy,  
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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Dr. Malakooti Seyyed Kazem

##### Street address

Iran University of Medical Sciences, Shahid Hemmat  
Highway, Tehran, Iran

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##### Province

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1348715459

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PR@iums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Iran University of Medical Sciences

#### 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

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Rezaie Khaled

##### Position

Phd student of Physiotherapy, Iran University of  
Medical Sciences

##### Latest degree

Master

##### Other areas of specialty/work

Physiotherapy

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Maddadkaran St., Shahid Nazari St., Mother Square,  
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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

### Contact

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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

Not applicable

### Analytic Code

Not applicable

### Data Dictionary

Not applicable

### Title and more details about the data/document

The original data is shared in thesis format

### When the data will become available and for how long

After defense of thesis, the original data is shared in  
thesis format.

### To whom data/document is available

Academic researchers, physiotherapists

### Under which criteria data/document could be used

In order to use clinical results, the original data is shared  
in thesis format.

### From where data/document is obtainable

Library of the faculty of rehabilitation rehabilitation  
Sciences of Iran University of Medical Sciences

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

Referral to library of the faculty of rehabilitation Sciences  
of Iran University of Medical Sciences

### Comments