

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Rocabado exercises vs. Myofascial Release: Comparative effects in patients with Temporomandibular Joint Dysfunction

#### Protocol summary

##### Study aim

The aim of this study was to compare the effects of Rocabado exercises and myofascial release on pain and jaw mobility in patients with temporomandibular joint dysfunction.

##### Design

A single-blinded, randomized clinical trial was conducted with thirty participants included by using convenient sampling technique.

##### Settings and conduct

The study settings included physical therapy out patient departments of Allied Hospital and Madinah Teaching Hospital, Faisalabad. The participants were blinded of the treatment given to them.

##### Participants/Inclusion and exclusion criteria

The participants having age 18 to 30 years with mild to moderate temporomandibular joint dysfunction according to fonseca questionnaire and mild to moderate pain levels on numeric pain rating scale with restricted mouth opening were included in the study. the subjects with the history of any recent surgery, temporomandibular joint (TMJ) hypermobility, severe osteoporosis, unhealed fracture of mandible and advanced diabetes were excluded.

##### Intervention groups

There were two interventional groups named as group A (Rocabado exercises) and group B (Myofascial release technique). The participants of group A received a set of six exercises named as Rocabado exercises as a treatment. These six exercises included rest position of tongue, shoulder posture correction, stabilized cervical flexion, axial extension of neck, controlled TMJ rotation and rhythmic stabilization technique. The participants of group B received myofascial release technique as a treatment approach which included the myofascial release of masseter and temporalis muscles.

##### Main outcome variables

The main outcome variables were severity of dysfunction, pain, functional limitation and mouth

opening range of motion.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221006056105N2**

Registration date: **2024-05-06, 1403/02/17**

Registration timing: **retrospective**

Last update: **2024-05-06, 1403/02/17**

Update count: **0**

##### Registration date

2024-05-06, 1403/02/17

##### Registrant information

##### Name

Saman Salahuddin

##### Name of organization / entity

Madinah Teaching Hospital Faisalabad

##### Country

Pakistan

##### Phone

+92 337 7002916

##### Email address

hashmisaman88@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-02-01, 1402/11/12

##### Expected recruitment end date

2024-04-12, 1403/01/24

##### Actual recruitment start date

2024-02-05, 1402/11/16

##### Actual recruitment end date

2024-04-05, 1403/01/17

**Trial completion date**

2024-04-30, 1403/02/11

**Scientific title**

Rocabado exercises vs. Myofascial Release: Comparative effects in patients with Temporomandibular Joint Dysfunction

**Public title**

Rocabado exercises vs. Myofascial Release: Comparative effects in patients with Temporomandibular Joint Dysfunction

**Purpose**

Treatment

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

Age 18 to 30 years Mild to Moderate temporomandibular joint dysfunction according to fonseca questionnaire Decreased mouth opening Mild to moderate pain on NPRS Male and female participants Willingness to participate

**Exclusion criteria:**

Any recent surgery Unhealed fracture of mandible Severe osteoporosis TMJ hypermobility Advanced diabetes

**Age**

From **18 years** old to **30 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **30**

Actual sample size reached: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization process was done using chit and draw or lottery method. Thirty chits were made in order to allocate the participants in both groups. Thirty chits were made and with every participant coming, one chit was drawn and it happened in a way that all even numbered chits were allocated into group A while all odd ones into group B.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The treatment techniques used in this study are soft tissue techniques out of which one was manual and the other was exercise based. Both groups received a baseline treatment in which therapeutic ultrasound was used so the groups were similar and comparable in order to blind the participants. The groups were homogenous at baseline i.e. of same age group and of similar levels of pain and severity of dysfunction. The interventions in the two groups were sufficiently similar in terms of implementation without the use of any kind of instrument in either group.

**Placebo**

Not used

**Assignment**

Other

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

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of the university of Faisalabad

**Street address**

P 175 Shadman Town Sargodha Road

**City**

Faisalabad

**Postal code**

38000

**Approval date**

2024-02-17, 1402/11/28

**Ethics committee reference number**

TUF/DR/SA/MSPP/2024/379

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

Temporomandibular Joint Dysfunction

**ICD-10 code**

M26.60

**ICD-10 code description**

Temporomandibular joint disorder, unspecified

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

Mouth Opening Range of Motion

**Timepoint**

It was measured before and after intervention.

**Method of measurement**

A ruler calibrated in millimeters was used to measure this outcome.

**2****Description**

Functional Limitation of Jaw

**Timepoint**

it was measured before and after treatment i.e. at baseline and at 4th week.

**Method of measurement**

Jaw Functional Limitation Scale was used to measure it.

## Secondary outcomes

### 1

#### Description

Pain

#### Timepoint

it was measured before treatment and after treatment.

#### Method of measurement

Numeric pain rating scale was used

### 2

#### Description

Severity of dysfunction

#### Timepoint

before and after treatment

#### Method of measurement

Fonseca Anamnestic Index Questionnaire was used.

## Intervention groups

### 1

#### Description

Intervention group: The participants of group A received therapeutic ultrasound (3 MHz, 1.2 W/cm<sup>2</sup> for 3 minutes) over TMJ and simple jaw exercises as a baseline treatment. then they were given an exercise protocol which was named as Rocabado exercises which included a set of six different exercises. each exercise was repeated for 6 six times. the treatment was given thrice a week over a period of 4 weeks.

#### Category

Rehabilitation

### 2

#### Description

Intervention group: The participants of group B received therapeutic ultrasound (3 MHz, 1.2 W/cm<sup>2</sup> for 3 minutes) over TMJ and simple jaw exercises as a baseline treatment. then they were given myofascial release technique for masseter and temporalis muscles. the participants were made to assume the side-lying position with affected TMJ on the top. gel was applied over these areas and then the muscles were slowly released. the treatment was given thrice a week over a period of 4 weeks.

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Allied Hospital Faisalabad

**Full name of responsible person**

Dr. Mariam Mehmood

**Street address**

P 175 Shadman Town Sargodha Road

#### City

Faisalabad

#### Postal code

38000

#### Phone

+92 337 7002916

#### Email

hashmisaman5@gmail.com

#### Web page address

### 2

#### Recruitment center

**Name of recruitment center**

Madinah Teaching Hospital

**Full name of responsible person**

Dr. Kishwar Batool

**Street address**

Sargodha Road

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**Postal code**

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#### Phone

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#### Email

hashmisaman5@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

The University Of Faisalabad

**Full name of responsible person**

Saman Salahuddin

**Street address**

P 175, Shadman Town, Sargodha Road Faisalabad

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#### Phone

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**Grant name**

**Grant code / Reference number**

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

No

**Title of funding source**

Madinah Teaching Hospital

**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**

Madinah Teaching Hospital Faisalabad

**Full name of responsible person**

Saman Salahuddin

**Position**

Physiotherapist

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

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**Person responsible for scientific inquiries**

**Contact**

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Madinah Teaching Hospital Faisalabad

**Full name of responsible person**

Saman Salahuddin

**Position**

Physiotherapist

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Madinah Teaching Hospital Faisalabad

**Full name of responsible person**

Saman Salahuddin

**Position**

Physiotherapist

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable