

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparative effects of Rocabado's Approach versus Jaw and Stick exercises on Pain, Range of motion and Disability among patients with Temporomandibular joint dysfunction

Protocol summary

Study aim

To Compare the Effects of Rocabado's approach versus Jaw and Stick Exercises on Pain, ROM and Disability among patients with Temporomandibular Joint Dysfunction

Design

It will Single blinded randomized clinical trial with parallel group design. 23 Participants will be allocated to two groups equally by random computer number generator

Settings and conduct

It will be conducted at Rashid Latif Dental Hospital. Outcome assessor will be kept blind.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: • Both male and female patients between age 20-60 years. Patients with mild to moderate TMJ dysfunction (according to Fonseca Questionnaire) • Patients with jaw pain and limited jaw range of motion, and limited mouth opening and associated joint pain • Patients with TMJ clicking sounds Exclusion Criteria: • Patients with a history of significant trauma of fractures to the jaw or temporomandibular joint, Patients with a history of systemic rheumatic diseases affecting the temporomandibular joint. Patients with severe TMJ dysfunction with recent oral surgeries were excluded

Intervention groups

Group A: will receive Rocabado approach with baseline treatment. Group A will receive Rocabado's approach consisting 6 exercises six times a day twice per week for four weeks. Group B: will receive Jaw and Stick Exercise with baseline treatment. Group B will receive Jaw and stick exercises with the frequency of 2 sets and 6 repetitions twice a day two times per week for four weeks

Main outcome variables

Pain: Numeric Pain Rating Scale (NPRS) ROM: Universal Goniometer Disability: Temporomandibular disorder (TMD) disability index questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220701055331N7**

Registration date: **2025-04-08, 1404/01/19**

Registration timing: **registered_while_recruiting**

Last update: **2025-04-08, 1404/01/19**

Update count: **0**

Registration date

2025-04-08, 1404/01/19

Registrant information

Name

Ifra Zulqarnain Awan

Name of organization / entity

Rashid Latif Medical College

Country

Pakistan

Phone

+92 333 4975431

Email address

ifra.awan@rlmc.edu.pk

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-03-20, 1403/12/30

Expected recruitment end date

2025-07-20, 1404/04/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative effects of Rocabado's Approach versus Jaw and Stick exercises on Pain, Range of motion and Disability among patients with Temporomandibular joint dysfunction

Public title

Comparative effects of Rocabado's Approach versus Jaw and Stick exercises on Pain, Range of motion and Disability among patients with Temporomandibular joint dysfunction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

- Both male and female patients between age 20-60 years. Patients with mild to moderate TMJ dysfunction (according to Fonseca Questionnaire)
- Patients with jaw pain and limited jaw range of motion, and limited mouth opening and associated joint pain
- Patients with TMJ clicking sounds

Exclusion criteria:

- Patients with a history of significant trauma of fractures to the jaw or temporomandibular joint, Patients with a history of systemic rheumatic diseases affecting the temporomandibular joint. Patients with severe TMJ dysfunction with recent oral surgeries were excluded

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

Random computer number generator will be used for randomization. Assign unique identification numbers to participants, then use a reliable software tool to generate a list of random numbers. Match these numbers to participant IDs and allocate individuals to different study groups based on the sorted random numbers. Ensure that the randomization process is concealed and documented for transparency and integrity.

Blinding (investigator's opinion)

Single blinded

Blinding description

Single blinding in a study involves keeping the outcome assessor blind to the intervention received by the participants. This helps to minimize bias in assessing the study outcomes. To achieve single blinding, the outcome assessor is not informed about the treatment allocation of the participants and remains unaware of which group received the intervention being studied.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Institutional Review Board of Rashid Latif Medical College, Lahore.

Street address

35-KM Ferozepur Road Lahore

City

Lahore

Postal code

54840

Approval date

2024-08-05, 1403/05/15

Ethics committee reference number

IRB/2024/157

Health conditions studied

1

Description of health condition studied

Temporomandibular joint dysfunction

ICD-10 code

M26.6

ICD-10 code description

Temporomandibular joint disorders

Primary outcomes

1

Description

Pain

Timepoint

Before intervention and 4 weeks after intervention

Method of measurement

Numeric pain rating scale to measure pain

2

Description

Range of motion

Timepoint

Before intervention and 4 weeks after intervention

Method of measurement

Range of motion will be measured by Universal goniometer

3

Description

Disability

Timepoint

before intervention and 4 weeks after intervention

Method of measurement

TMD Disability Index will be used to measure disability

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Group A - Rocabado's Approach:
Group A will receive Rocabado's approach consisting 6 exercises six times a day twice per week for four weeks.

Category

Rehabilitation

2

Description

Intervention group: Group B- Jaw And Stick Exercises:
Group B will receive Jaw and stick exercises with the frequency of 2 sets and 6 repetitions twice a day two times per week for four weeks

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Rashid Latif Dental Hospital

Full name of responsible person

Dr. Ifra Zulqarnain Awan

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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rashid latif medical college

Proportion provided by this source

100

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

Rashid latif medical college

Full name of responsible person

Tahreem Waseem

Position

Physiotherapist

Latest degree

Bachelor

Other areas of specialty/work

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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

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

Analytic Code

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

Data Dictionary

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

Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Other areas of specialty/work

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