Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
Street address
35-km ferozepur road Lahore
City
Lahore
Postal code
54840
Phone
+92 333 4975431
Email
ifra.awan@rlmc.edu.pk

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rashid latif medical college
Full name of responsible person
Ifra Zulqarnain Awan
Street address
35-km ferozepur road lahore
City
lahore
Postal code
54840
Phone
+92 333 4975431
Email
ifra.awan@rlmc.edu.pk
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
Physiotherapy
Street address
35-km ferozepur road lahore
City
lahore
Province
punjab
Postal code
54840
Phone
+92 321 1721917
Email
tahreemwaseem4@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Rashid Latif Medical College

Full name of responsible person
Ifra Zulqarnain Awan
Position
Physiotherapist
Latest degree
Master
Other areas of specialty/work
Physiotherapy
Street address
Rashid Latif Medical College 35-km Ferozpur Road
Lahore
City
Lahore
Province
Punjab
Postal code
54840
Phone
+92 333 4975431
Fax
Email
ifra.awan@rlmc.edu.pk

Person responsible for updating data

Contact
Name of organization / entity
Rashid Latif Medical College
Full name of responsible person
Ifra Zulqarnain Awan
Position
Physiotherapist
Latest degree
Master
Other areas of specialty/work
Physiotherapy
Street address
Rashid Latif Medical College 35-km Ferozpur Road
Lahore
City
Lahore
Province
Punjab
Postal code
54840
Phone
+92 333 4975431
Fax
Email
ifra.awan@rlmc.edu.pk

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