DOI: 10.7860/JCDR/2025/75164.21562

Research Protocol

Physiotherapy Section

Efficacy of Ischaemic Compression Technique, Strain Counterstrain Technique, and Conventional Exercises in Myofascial Temporomandibular Disorder: A Protocol for Randomised Control Trial

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ABSTRACT

Introduction: Temporomandibular Joint Dysfunction (TMD) encompasses a variety of disorders affecting the Temporomandibular Joint (TMJ) and associated muscles. These conditions can significantly impact an individual's quality of life, causing pain, limited jaw movement, and difficulties in daily functional activities. Myofascial TMD, characterised by muscle pain and tenderness, is one of the most common forms of this disorder. Existing treatment methods often include exercise techniques aimed at reducing pain and improving jaw function.

Need for the Study: The Strain Counterstrain Technique (SCT) has the potential to provide a patient centered, non invasive, and holistic approach to resolving the issues associated with these complex conditions. Further research into this technique is necessary for addressing TMJ disorders. This research will enhance the scientific understanding of its effectiveness and, consequently, improve treatment outcomes and management strategies for TMJ diseases in general. To enhance our understanding and patient outcomes, it is imperative to examine the Strain Counterstrain approach in TMJ disorders.

Aim: To evaluate and compare the effectiveness of three different exercise techniques in treating myofascial TMD: Ischaemic Compression Technique (ICT), SCT, and conventional exercises.

Materials and Methods: A Randomised Controlled Trial (RCT) will be conducted at Acharya Vinoba Bhave Rural Hospital from February 2024 to June 2025. The study will include individuals aged 18 to 65 with a confirmed diagnosis of myofascial TMD. Thirty participants will be randomly assigned to each of the three treatment groups (ICT, SCT, and Conventional Exercises), comprising a total sample size of 90. The parameters to be assessed include pain levels using the Numerical Pain Rating Scale (NPRS); active mouth opening, measured with a mandibular goniometer; and functional activities, assessed using the Jaw Functional Limitation Scale (JFLS). Continuous outcome variables will be examined using normality tests and summarised using descriptive statistics. Significance will be determined using ANOVA tests for normally distributed data and Kruskal-Wallis tests for non-normally distributed data. Categorical variables will be summarised by frequency and percentage, and Chi-square tests will be used to measure efficacy. A p-value of <0.05 will be considered significant.

Keywords: Jaw functional limitation scale, Mouth opening, Physiotherapy, Rehabilitation, Rocabado exercises, Trigger point

INTRODUCTION

The TMD refers to conditions affecting the TMJ and surrounding muscles. The TMJ, located in front of the ears, connects the mandible to the temporal bone. Approximately 60-70% of the population exhibit signs of TMD, though only 25% experience symptoms. Severe cases occur in 1-2% of children, 5% of teenagers, and 5-12% of adults [1]. The TMJ, a compound joint, enables translatory and hinge-like movements through the mandibular condyle, temporal bone, and articular disc. The masseter, temporalis, and pterygoid muscles regulate jaw function [2]. TMD results from musculoskeletal dysfunction, stress, bruxism, clenching, or poor posture and is often associated with anxiety, depression, fibromyalgia, and chronic pain [2].

TMD symptoms include pain in the face, neck, and shoulders, joint noises, jaw locking, ear-related issues, and psychosocial effects. The most common symptom is localised TMJ or masticatory muscle pain [3]. TMD encompasses joint dysfunction and myofascial pain, leading to generalised muscular discomfort [4]. Management of TMD includes various therapeutic approaches aimed at reducing pain and improving jaw function [2].

The ischaemic compression technique involves applying sustained pressure to trigger points in the masticatory muscles to relieve tension and restore normal blood flow. The SCT is a passive manual therapy that alleviates muscle tightness by positioning the affected muscle in a pain free state, promoting relaxation and function. Conventional exercises, such as jaw stretching, strengthening, and relaxation techniques, help enhance TMJ mobility, reduce stiffness, and alleviate symptoms associated with TMDs [2-5].

Physical therapy enhances oral function while reducing discomfort and inflammation [5]. The SCT may help patients with localised muscular pain by improving function and reducing pain. Meseguer A et al., (2006) conducted a study on the benefits of the SCT in reducing mechanical pain sensitivity of tender spots in the upper trapezius muscle and concluded that the SCT was effective in reducing tenderness in these areas. The application of a longitudinal stroke during the strain counterstrain did not influence the effectiveness of the classical description of the technique [6].

The clinical use of Rocabado's 6x6 exercise regimen as a conservative TMD treatment has been widespread. The Rocabado 6×6 workout program is designed specifically for individuals with TMDs. It helps facilitate the flow of synovial fluid over the articular

surfaces, improves circulation, nourishes the joint, and eliminates articular cartilage metabolites, all of which help release the masticatory muscles and alleviate discomfort [3].

Primary objective:

1) To determine the efficacy of ischaemic compression in TMDs.
2) To determine the efficacy of the SCT in TMDs.
3) To determine the efficacy of traditional exercises in TMDs.

Secondary objectives: To compare the effects of standard exercises, the strain counterstrain approach, and ischaemic compression in myofascial TMDs.

Null hypothesis: There will be no significant difference in the effectiveness of traditional exercises, ischaemic compression, and SCT in myofascial TMDs.

Alternative hypothesis: There will be a significant difference in the effectiveness of traditional exercises, ischaemic compression, and SCT on pain, active mouth opening, and functional activities in myofascial TMDs.

REVIEW OF LITERATURE

Myofascial trigger points are commonly implicated in TMDs, leading to muscle tension, restricted jaw movement, and chronic discomfort. Effective management of these trigger points is crucial for improving patient outcomes. The ischaemic compression technique is a manual therapy aimed at alleviating pain and enhancing functionality in individuals with TMDs. This approach involves applying sustained pressure to trigger points in the masseter muscle and other related musculature of the TMJ.

Studies on the efficacy of ischaemic compression have consistently shown its benefits in relieving pain and improving functionality, particularly in cases involving myofascial trigger points. In a pilot study by Azam I et al., a rehabilitation program combining SCT, phonophoresis, heat therapy, and stretching demonstrated significant pain reduction and improved jaw function in TMD patients [2]. Similarly, Saleem S et al., compared ischaemic compression and SCT in 36 participants with upper trapezius trigger points, finding both techniques equally effective in reducing pain and enhancing active mouth opening after a four week intervention [7].

Pawar PA et al., reported significant improvements in pain and ankle dorsiflexion using the SCT for plantar fasciitis [8]. Lewis C et al., found immediate increases in pressure pain threshold after strain counterstrain treatment for low back pain; however, these effects were not sustained [9]. Segura-Ortí E et al., conducted a study comparing trigger point dry needling with strain counterstrain, revealing no significant differences [10], while Christopher Kevin Wong confirmed the efficacy of the SCT for pain reduction at tender points [11].

A study by Mulla NS et al., concluded that Rocabado's technique, when combined with conventional TMJ exercises, demonstrates statistically and clinically significant improvements in subjects with TMD compared to using conventional exercises alone [12]. Given the growing emphasis on evidence-based clinical practice, this study seeks to address the gap in the literature by comparing the efficacy of ischaemic compression and SCT. The findings are expected to provide valuable insights for clinicians, guiding the selection of effective interventions for patients with myofascial TMDs. Hence, the present study will be conducted to evaluate and compare the effects of ischaemic compression, SCT and conventional exercises on pain, active mouth opening, and functional activities in patients with myofascial TMDs.

MATERIALS AND METHODS

A three-arm parallel, single-blinded RCT will be conducted at Acharya Vinoba Bhave Rural Hospital from February 2024 to June 2025. Institutional Ethics Committee approval has been obtained on 31/01/2024, REF No. DMIHER(DU)/IEC/2024/166. The trial has been registered on the CTRI portal with the registration number CTRI/2024/04/066079.

Inclusion criteria:

1) Participants who are willing to take part in the study and provide written informed consent.
2) Participants aged between 18 and 65 years.
3) Confirmed cases of myofascial TMDs.
4) Presence of a trigger point in the medial and lateral pterygoid, temporalis, and masseter muscles.

Exclusion criteria:

1. Presence of subluxation or intra-articular/degenerative joint diseases requiring immediate treatment.
2. A history of surgery within the last three months involving the cervical region or TMJ.
3. Diagnosis of rheumatic conditions affecting the TMJ.
4. History of TMJ fracture.
5. Cognitive or perceptual disorders that may interfere with the study.
6. Presence of chronic pain conditions such as trigeminal neuralgia.

Sample size calculation: Sample size will be calculated using Cohen's effect size by comparing two means:

Effect size = d = μ2-μ1 σ=0.8 (Estimated)

Considering a large effect size difference of 0.8.

Sample size N = (1+r) (Z1−α2/+α1−β) 2 d2 + Z1−α/2 2 2 (1+r)

Z1−α2/at 5 % level of significance = 1.96

Z1−βat 80 % Power = 0.84

The minimum sample size required is 26 participants per group. Considering a 15% dropout rate, which equates to 4 participants, each group must have a total of 30 participants.

Patients meeting the inclusion criteria will be randomly assigned to three groups:

- Group A will undergo the ICT.
- Group B will receive the SCT.
- Group C will perform conventional exercises, all for three days a week over six weeks.

Group A: Ischaemic compression technique

- The patient will be asked to lie in a supine position with the cervical spine in a neutral posture to facilitate the procedure. The physiotherapist will locate the major trigger point on the surface of the masseter muscle. Once the trigger point is identified, pressure will be applied progressively until it feels painful. The duration of this pressure will be 90 seconds. If the patient reports a reduction in pain or discomfort by about half, the pressure will be increased until the pain or discomfort returns [3].

Group B: Strain/Counterstrain Technique (SCT)

- **Masseter muscle:** The subject will lie supine. The Physical Therapist (PT) will identify a tender spot on the anterior border of the masseter muscle and the anterior edge of the mandibular ascending ramus. The patient's jaw will be pushed to the side of the painful region until the discomfort is minimised, shortening the masseter muscle. This position will be maintained for ninety seconds, followed by a 5-second break before carefully returning the jaw to a neutral position.
- **Medial pterygoid muscle:** The PT will sit behind the participant, targeting the medial pterygoid muscle. The open jaw will be pushed laterally by the PT, away from the treatment side. After

maintaining this position for 90 seconds and taking a 5-second break, a stabilising force will be applied with the forearms against the opposite side of the forehead until discomfort is minimised. The therapist will then gradually return the participant's jaw to its neutral position.

- **Lateral pterygoid muscle:** The participant will lie in a supine position while the instructor stands behind the patient and locates the tender site 1 cm in front of the condyle's neck, beneath the zygomatic arch. While maintaining head stability, the participant's jaw will be opened laterally to the side opposite the tender point. After holding this position for ninety seconds, the participant's jaw will be gradually returned to the neutral position while monitoring the tender region closely [2].

Group C: Rocabado exercises

- Rocabado's 6×6 exercises [Table/Fig-1].
- This program includes six exercises to be performed six times a day, with each exercise repeated six times.

Intervention	Rationale	Dosage
1. Rest position of the tongue	Encourages diaphragmatic breathing to lessen the accessory muscles' activity.	6 repetitions X 6 sets
2. Shoulder posture	Correction of abnormal scapular protraction	6 repetitions X 6 sets
3. Stabilised head flexion	This allows the posterior cervical muscles to elongate.	6 repetitions X 6 sets
4. Axial extension of the neck	Reduces tension in the supra- and infrahyoid muscles and improves the masticatory muscles' capacity for relaxation.	6 repetitions X 6 sets
5. Control of TMJ rotation	Reduces masticatory muscle activity and joint overload.	6 repetitions X 6 sets
6. Rhythmic stabilisation technique	Through proprioception, rhythmic stabilisation also encourages the right position for the jaw to rest.	6 repetitions X 6 sets
7. Phonophoresis using therapeutic ultrasound	Reduces pain and inflammation	Frequency - 1 MHz Mode - Continuous Intensity - 1,5 W/cm2 Time - 15 min

[Table/Fig-1]: Conventional exercises with ultrasound.

Outcome Measures

1) **Numerical Pain Rating Scale (NPRS):** The NPRS will be used to assess pain [6]. It is a widely used, simple, and reliable tool for measuring pain intensity in adults, employing an 11 point scale ranging from 0 (no pain) to 10 (the worst pain imaginable).
2) **Jaw Functional Limitation Scale (JFLS):** The JFLS is a tool for assessing the functional limitations of the jaw in individuals, particularly those with TMDs. It evaluates three key constructs:

- Mastication
- Vertical Jaw Mobility
- Emotional and Verbal Expression [13].

Range of motion: To assess the range of motion of the TMJ, a half-circle goniometer (Brand: Medisky Surgicals Goniometer) will be used [14].

All these parameters will be assessed at baseline, three weeks, and six weeks, before and after the intervention.

STATISTICAL ANALYSIS

Statistical Package for the Social Sciences (SPSS) version 22.0 will be used for statistical analysis. Baseline characteristics for demographic variables will be detailed by frequency and percentage for categorical data, and by mean and standard deviation for continuous data. The normality of continuous outcome variables will be assessed using the Kolmogorov-Smirnov test at a 5% significance level ($p<0.05$). If the data fails this test, it will be deemed non-normal, and a non parametric test will be utilised to determine significance. For intergroup comparisons, ANOVA will be applied. For non-normal data, measures such as mean, median, and lower and upper quartiles will be utilised, and significance will be assessed using the Kruskal-Wallis test. Categorical variables will be summarised by frequency (N) and percentage (%), with their efficacy determined through Chi-square analysis. A p-value of less than 0.05 will be considered statistically significant.

Consent and assent: Participants enrolled in the study will be informed about the study, and each will provide informed consent and assent.

Confidentiality: Any information regarding the study's participants will be kept strictly confidential. Patient-related information will only be utilised with the patients' approval.

Data access: The study's Principal Investigator (PI) is responsible for storing and maintaining all data acquired during and after the trial. The PI will have access to the final trial dataset, which will be shared in de-identified form only after receiving a written request for research and publication purposes.

Ancillary and post-trial care: The PI will provide care to research participants in the event of an occurrence that causes injury as a result of trial participation, in accordance with Ravi Nair Physiotherapy College and DMIHER policy.

Dissemination policy: Any data acquired during or after the study will be utilised solely for academic and research purposes, culminating in a publication in a reputable journal.

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PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: Aug 30, 2024
- Manual Googling: May 03, 2025
- iThenticate Software: May 06, 2025 (13%)

ETYMOLOGY: Author Origin

EMENDATIONS: 9

AUTHOR DECLARATION:
- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. NA

Date of Submission: **Aug 29, 2024**
Date of Peer Review: **Nov 19, 2024**
Date of Acceptance: **May 08, 2025**
Date of Publishing: **Oct 01, 2025**