Efficacy of Myofascial Release Therapy and Positional Release Therapy in Patients with Upper Trapezius Trigger Points: Study Protocol of a Double-blinded Randomized Clinical Trial

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Background: Myofascial trigger points are incredibly prevalent and are a painful aspect of almost everyone's life at some point. Myofascial trigger point pain can be excruciating and severely impair the quality of life. Therefore, in patients with neck pain caused by upper trapezius trigger, this current clinical trial will demonstrate the effectiveness of myofascial release therapy and positional release therapy in improving the level of pain, neck impairment, pain threshold, and standard of life.

Methods: A double-blinded randomized clinical trial will be conducted. Fifty-two participants with active myofascial trigger points in the upper trapezius muscle will be recruited based on selection criteria. They will be randomly allocated into group A (conservative treatment + myofascial release technique) or group B (conservative treatment + positional release technique). Both groups will receive the intervention three times a week for 2 weeks. The study will use the Numeric Pain Rating Scale, pressure algometer, Neck Disability Index, and a 36-Item Short-form Questionnaire as outcome measures.

Discussion: This trial will help identify the effectiveness of the positional and myofascial release techniques in active upper trapezius muscle trigger points and their effect on physical parameters.

Trial Registration: This trial has been prospectively registered at the Clinical Trials Registry-India (CTRI/2023/07/055126) on 12 July 2023.

KEYWORDS: Myofascial release therapy; pain threshold; quality of life; trapezius muscle; trigger point trial

INTRODUCTION

Myofascial trigger points (MTrPs) are the most prevalent hallmark of an umbrella term of regional pain illness known as myofascial pain syndrome (MPS).[1] MPS can arise from activities that include chronic bad posture or repetitive usage of the same muscle area, such as in office workers.[2] The latter is distinguished by the existence of one or more trigger points (TPs), frequently located in the upper trapezius (UT). With 45–54% of the general population experiencing neck discomfort, neck pain is becoming a more significant health problem in the 21st century.[3]

MTrPs or hyperirritable nodules are believed to result from motor endplate dysfunction and are located inside a tight band of a muscle. The MTrP region is sensitive to compression and may exhibit motor dysfunction, autonomic abnormalities, and a typically referred pain pattern.[4]

MTrPs can be either active or latent and are characterized by hyperirritable regions inside tight bands of skeletal muscle. While latent MTrPs only produce local and referred pain in response to direct pressure, active MTrPs are linked to spontaneous local and referred pain. MPS is the aggregate term for active MTrPs in a particular body location. Like active MTrPs, latent MTrPs may result in peripheral and central

sensitization, as well as allodynia near the trigger point position and hyperexcitability distant from the MTrPs once pressure is applied. Motor, sensory, and autonomic components are present in both active and latent MTrPs. Latent motor-muscle pain proteins are common in healthy populations.[5] Active TrPs are those that, when stimulated, fully or partially replicate any symptom that a patient has, and in such a way that the patient recognizes the replicated symptom as a familiar experience.[6] A multitude of chronic pain conditions, such as tension-type headaches,[7] migraines,[8] temporomandibular pain,[9] mechanical neck pain,[10] whiplash-associated neck pain,[11] shoulder discomfort,[12] lateral epicondylalgia,[13] or low back pain are more prone to develop latent trigger points.

Office workers are experiencing a persistent and growing issue with neck and shoulder pain due to their jobs. The task induces significant levels of ocular, postural, and cognitive stress in addition to extended low-level static exertions, which contributes to its multifactorial etiology.[14]

The main clinical manifestations of TPs are typically present in one or more of the following patients: reduced force, decreased range of motion (ROM), pain when applying compression or stretch to the muscle, pain-related muscle weakening without muscle atrophy, local pain, referred pain based on a typical pattern, and local twitch response triggered by the snapping palpation of the taut band. Reduced functioning and standard of life may arise from a combination of these symptoms.[3] Untreated, long-term instances may cause symptoms including sadness, exhaustion, and behavioral abnormalities in addition to local or regional discomfort.[15]

Previous studies have employed a variety of treatments such as local anesthetics (botulinum toxin injection, dry needling), electrotherapy modalities (transcutaneous electrical nerve stimulation, ultrasound, low-level laser therapy, electromyography), manual therapies (spray and stretch technique, deep pressure massage, mechanical vibration, ischemic compression), muscle biopsy, heat therapy, manipulative therapies, and magnet therapies.[16,17]

One of the most important forms of treatment for MTrPs is manual therapy. Under manual therapy, myofascial release (MFR) is one technique for treating trigger points in the trapezius. It improves lymphatic and vascular drainage while relaxing stiff muscles. It operates by modifying the viscoelastic properties of connective tissue. Correct muscular alignment is restored. MFR in the form of direct physical contact entails extending the muscle from its origin to its insertion and deep transverse friction massage from the palm's ulnar border.[18]

Another variation of manual therapy for treating trigger points is positional release therapy (PRT). By employing passive body alignment, this technique is said to relieve pain and trigger point discomfort as well as musculoskeletal issues over an extended period.[19] PRT depends on precisely arranging damaged tissue to cause an uncontrollably high level of tension and/or spasm to be released or reduced. Circulatory advancement, decreased nociceptive sensitivity, and spindle resetting are considered to be the processes involved.[20]

To the best of the authors' knowledge, no studies have compared MFR with conventional treatment and PRT along with conventional treatment in the management of MTrPs of the UT muscle. Hence, this study will aim to assess the effect of MFR with conventional treatment and PRT along with conventional treatment on pain intensity, pain pressure threshold (PPT), neck disability, and standard of life in MTrPs of UT muscle patients.

MATERIALS AND METHODS

Study Design

A double-blinded pretest–posttest experimental study will be executed in which participants with active MTrPs of the UT muscle will be recruited based on a set of criteria that are mentioned subsequently. They will then be randomly assigned to one of the two groups, group A (PRT) or group B (MFR), using computer-generated block randomization. To avoid any kind of biasing, the participants and outcome evaluator will be blinded. Sequentially numbered, opaque sealed envelopes will be prepared by the chief investigator using a randomly formed list. The trial will follow the procedure as per the CONSORT guidelines[21] (Figure 1).

The study has got ethical clearance from the Institutional Ethical Committee

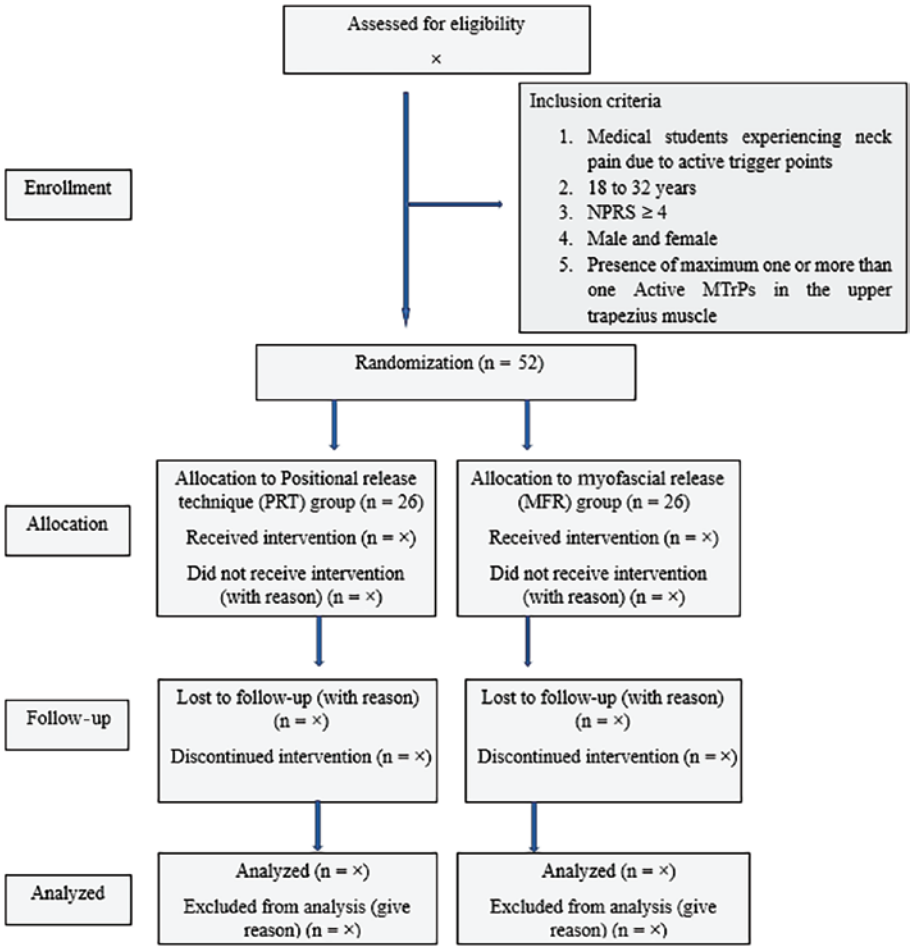

Figure 1. Consort flow diagram.

(IEC) number 2410. This trial has been prospectively registered at the Clinical Trial Registry—India (CTRI) number CTRI/2023/07/055126. The Universal Trial Number (UTN) is U1111-1292-8483.

The study will be conducted at the Maharishi Markandeshwar Institute of Physiotherapy and Rehabilitation, Maharishi Markandeshwar (Deemed to be University), Mullana-Ambala, Haryana. The trial will be conducted in the physiotherapy outpatient department in a tertiary-care hospital.

Inclusion and Exclusion Criteria

This study will be recruited under the Physiotherapy OPD, MMIPR, MM (DU), Mullana-Ambala. The participants will be recruited according to their eligibility criteria as mentioned in Table 1. The potential participants will undergo the pre-assessment to provide additional information to confirm their eligibility before the baseline evaluation. The participants will be taken under the written consent form.

Recruitment of Participants

A total of 52 patients with UT trigger points will be recruited for the study according to the selection criteria using purposive sampling. Demographic data such as name, age, gender, occupation, address, and contact number will be taken in a pre-designed pro forma of the patients. Every patient's height and weight will be recorded to determine their body mass index.

Sample Size Calculation

The differences in the primary outcome from the study by Stieven et al. were taken into account for sample size estimation where the PPT of the UT muscle measured using a pressure algometer is considered

TABLE 1. Showing Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
• Medical students experiencing neck pain due to active trigger points • 18–32 years • NPRS ≥4 • Male and female • Presence of maximum one or more than one Active MTrPs in the upper trapezius muscle	• Previous history of trauma or fracture of the cervical spine • PIVD at the cervical region • Any inflammatory pathology, pregnant females, neurological impairment, and cervical tumor • Neck deformities such as scoliosis or torticollis • Signs of radiculopathy or myopathy • Cervical spine surgery • Patients who received pharmacological treatments and any other types of management (acupuncture, acupressure, dry needling, etc.)

MTrPs = myofascial trigger points; NPRS = Numeric Pain Rating Scale; PVID = prolapsed intervertebral disc.

as the primary outcome measure. The resultant effect size (d) of 0.8, with a two-tailed hypothesis, calculated a sample size of a total of 52 participants at $\alpha = 0.05$ and power (1-β) of 80% keeping the allocation ratio N2/N1 to 1.[22]

Interventions

Patients will be assessed for active trigger points in the UT muscle by using manual palpation and identified using a pressure algometer (PA). A written consent form will be taken from the patients for voluntary participation. Patients will be recruited based on the selection criteria. Group A (PRT group) will receive PRT with conventional treatment, and group B (MFR group), will receive MFR with conventional treatment. Conventional treatment included static stretching (SS) of the UT muscle and a cold pack for 8–10 min. Patients will receive six treatment sessions for 2 weeks, i.e., 3 days/week on consecutive days. Refer to Table 2 for the procedure and duration of the treatment.

All patients will be informed about the study procedure and treatment protocol in their native language, and written informed consent will be procured. The researcher will provide patients with an information sheet that explains the study protocol as well as the risks and benefits.

Outcome Assessment

A proper patient assessment will be done with the help of a detailed form in which patients' demographic information will also be recorded, including their name, age, gender, height, weight, and contact number. Throughout the treatment, all outcome measures will be evaluated two times: pre-intervention (on the first day) and post-intervention (on the 15th day). The study's principal investigator will provide the intervention. Repetitions of the treatment session will be reduced according to the pain severity.

Numeric Pain Rating Scale (NPRS)

The NPRS questionnaire is composed of an 11-point scale from 0 to 10. The patient chooses the most compatible value with the force of pain they have experienced in the last 24 h, in which "0" means no pain and "10" means intense pain. When generating data for statistical analysis, the NPRS has a considerably acceptable sensitivity. The patient has to mark the score on the questionnaire according to the pain intensity he/she is suffering. Hefford et al. reported that the reliability of NPRS is $r = 0.74$.[26]

Pain Pressure Threshold (PPT)

An orchid scientific algometer model ALGO-D-01, a dial-type PA with a range of up to 20 kg, will be used. It is calibrated in kg/cm^2. A PA's footplate area measures 1 cm. When a patient felt even the slightest amount of discomfort, we will tell them to express it. Every muscle group has three readings, with a 5-min break in between. It will be determined to take the minimum two numbers and average them.[27] To quantify discomfort and therapy impact in myofascial and musculoskeletal pain, a PA is a practical, affordable, clinically reliable, valid, and viable instrument. Excellent test–retest reliability and a decent interclass correlation coefficient (ICC; mean ICC = 0.75 and 0.84, respectively) are observed.[28,29] In addition, patients will be completing the following self-report measures.

TABLE 2. Interventions with Protocol and Duration

Intervention Name	Positioning	Procedure	Duration
PRT	**Therapist position:** Near the affected side of the patient **Patient position:** Supine	• By maintaining the cervical spine in a neutral state, the participant will be asked to lie supine and relaxed. • The therapist will progressively apply more pressure on the identified trigger points with his/her thumb. In the next step, the therapist will move into a more comfortable position which exerts less stress and reduces pain by up to 80%. • The therapist will passively sustain the patient's upper extremities in the abduction position for 90 s, with a 20-s rest period in between each repetition.[23]	Three repetitions for each session
MFR	**Therapist position:** Behind the patient **Patient position:** Ideal and comfortable sitting	• The patient will be made to remain in a sitting position with the knee slightly in front of the feet and the patient's feet firmly planted on the ground, with the hips higher than the knees. • The therapist will be standing at the backside of the patient. MFR on the UT will be performed, while the patient slowly rotates their head from side to side and drops their head forward. • The therapist will then apply pressure for 10 s to the opposite side of the rotation.[24]	Five repetitions for each session
Conventional treatment	**Therapist position:** Behind the patient **Patient position:** Sitting	1. **Static stretching:** Passive stretching will be applied to the UT muscle for five repetitions with a 20-s hold.[25] 2. **Cryotherapy:** The patient will receive a cold pack for 8–10 min after the treatment session	Five repetitions for each session

MFR = myofascial release; PRT = positional release therapy; UT = upper trapezius.

Neck Disability Index (NDI)

It is a commonly used 10-item self-report measure of disability resulting from neck pain. Every item covers a series of six comments on discomfort or challenges that impaired one's capacity to handle tasks associated with everyday life. The stable psychometric properties (α = 0.92) of this questionnaire suggest that it offers an objective means for assessing the functional disability of patients suffering from neck pain.[28]

36-Item Short-form Questionnaire (SF-36)

Eight domains are evaluated on the SF-36 quality-of-life questionnaire: physical capacity, physical role, physiological discomfort, general health, vitality, social activities, role-emotional, and mental health. The total score on this measure ranges from 0 (the lowest standard of life) to 100 (the best quality of life). The SF-36 questionnaire can distinguish between participants with medical issues and their healthy counterparts.[30] In several studies of both general and specialized populations, the SF-36 has been frequently used and shown to help determine the relative burden of various disorders and the health gains brought about by various treatments over time. Internal consistency was satisfactory for all (Cronbach's α = 0.728) subscales except Social Functioning (Cronbach's α = 0.527) and General Health (Cronbach's α = 0.693).[31]

Data Analysis

Data will be statistically analyzed through the Statistical Package for Social Sciences (SPSS) software.[32] An independent researcher will complete observable investigations and datasets. Descriptive statistics will be used to represent the demographic details of all the participants. The normality test, Kolmogorov–Smirnov test, will be used to check the normal distribution of the sample size. Based on the normality, descriptive statistics data will be expressed as mean, standard deviation, or median and interquartile range. A paired *t*-test or Wilcoxon signed rank test will be

made for the within-group comparison, and between groups, the comparison will be made through an independent *t*-test or the Mann–Whitney U test. The chi-square test will be used for nominal or ordinal data. Statistical significance will be set at $p \leq 0.05$ and clinical importance will be determined with a 95% confidence interval equivalent to moderate effect size. For all the analyses, the p-value will be set at ≤0.05 as significance.

DISCUSSION

However, it remains unclear whether the PRT and MFR are effective in active trigger points of the UT muscle. Therefore, this experimental trial will help to provide the PRT and MFR impact on parameters such as pain intensity and pressure threshold in individuals with neck pain due to the UT trigger points. This clinical trial's primary goal is to determine the effectiveness of the PRT technique and MFR technique on pain intensity, pain threshold, and standard of life among patients with active trigger points in the UT due to neck pain.

The secondary goal, which will be accomplished, is to compare the effect of MFR along with conventional treatment and PRT along with conventional treatment on the outcome measures. This trial will contribute to the evidence-based use of PRT and MFR with conventional treatment in the management of neck pain. It contemplates the items of checklists for protocol studies to minimize bias, and it was prospectively registered. Data will be published after the study is completed.

Current studies indicate that excessive stress or damage to muscle fibers is the first step in the pathogenesis of MPS and MTrPs consequences. This leads to a reduction in the quantity of nutrients and oxygen that are accessible, which causes protective and involuntary muscular contraction, and ultimately boosts the metabolic needs of the tissue. Myofascial discomfort may also result from eccentric muscle stresses and adaptive lengthening.[1]

According to another research, TrPs also cause large-diameter myelinated afferent nerve terminals that are non-nociceptive to become more sensitive. Based on these investigations, it is confirmed that the TrP region is a site of peripheral sensitization that may sensitize spinal and supraspinal neurons, supporting the presence of both nociceptive and non-nociceptive pain sensitivity. The reported effects of TrP spinal cord connections on dorsal horn neuronal neuroplastic alterations and their increased connectivity to a larger number of nociceptive neurons make this process extremely significant for musculoskeletal pain problems.[17]

Previous studies showed that MFR was effective in reducing pain and disability, and increasing the ROM. Hence it is concluded that MFR with a hot pack is an effective therapeutic option in treating active MTrPs in the UT muscle.[33-35] A study to determine the efficacy of PRT and therapeutic massage on pain, pain threshold, and muscle stiffness in patients with trigger points or tender points of the UT muscle concluded that, on comparing patients treated with PRT to those treated with therapeutic massage, they showed significant improvements in NPRS, PPT, and muscle stiffness.[36]

The recruitment strategy, diagnosis, and eligibility criteria to be employed in the study are purely based on regular clinical practice and are compatible with the findings which patients usually report at the physiotherapy outpatient department. The outcome measures to be used in the trial are easy to assess as well in the daily clinical practice.

To strengthen the rationality of the outcomes and to prevent biasing related to the selection of participants, computer-generated randomization will be performed. Further, the participants will remain blinded to the group allocation. To our knowledge, this will be one of the first trials comparing the PRT and MFR along with cold therapy and static stretching in patients with active trigger points of the UT muscle. Nevertheless, if any of these treatment approaches demonstrate effectiveness, it could represent a practical intervention with a substantial impact on individuals' pain, tenderness, and neck disability.

CONCLUSION

This study seeks to provide a piece of comprehensive information on the effect of PRT and MFR in managing pain, disability, and quality of life of individuals. This will attribute the preliminary work for medical students to consider the enticing technique as another form of treatment

for patients who experience neck pain due to active trigger points of the UT muscle. Additionally, it might provide important knowledge that can help influence healthcare policy and clinical decision-making.

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CONFLICT OF INTEREST NOTIFICATION

The authors declare there are no conflicts of interest.

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