

## Study Protocol

### **Effectiveness of Myofascial Release Vs High frequency TENS for Pain Relief and Functional improvement in College Students with Trapezius Myalgia: A Comparative Study**

#### **ABSTRACT**

**Background** – Trapezius Myalgia is characterized by pain in the trapezius muscle. The patient suffering from myalgia usually complains of pain, stiffness and tightness of the upper trapezius muscle. Acute or chronic neck-shoulder pain is the hallmark of this condition. The pain in the muscle usually lasts for few days or it can be even longer. The presence of spasm in upper trapezius muscle is shown by neck pain in the back of the neck and between the bases of the neck and the shoulder. This protocol has been created that describes the design of experimental study to evaluate and compare the effect of Myofascial Release (MFR) versus High-Frequency TENS for pain relief and functional improvement in subjects with Trapezius Myalgia.

**Methods** – The participants (n=45) will be recruited in the study suffering from Trapezius Myalgia and meeting the inclusion criteria. Two groups will be formed such that group A will be treated with Myofascial Release technique and group B will be treated with High Frequency TENS modality. The protocol will cover 4 weeks of treatment. Regular assessment will be carried out on 1<sup>st</sup> and 4<sup>th</sup> week of the rehabilitation period. During the rehabilitation period, we will evaluate pain status and functional improvement and range of motion of the neck in the subject at regular intervals. Our outcome measures will be – Numerical Pain Rating Scale (NPRS) and Neck Disability Index (NDI).

**Discussion-** The efficacy of the intervention will be evaluated by analyzing pain relief using Numerical Pain Rating Scale (NPRS) and functional improvement by using Neck Disability Index (NDI). The result of the study will significantly provide affirmation on using these modalities for treating myalgia patients.

**Keywords** – Trapezius Myalgia, Myofascial Release, High-Frequency TENS, Rehabilitation, Physiotherapy

## INTRODUCTION

Myalgia is usually known as muscle ache or muscle pain. Myalgia can occur in any muscle. In Trapezius myalgia, the patient complains of pain, stiffness and tightness of the upper trapezius muscle. Some studies show that along with tenderness of the upper trapezius area, sometimes occipital headache and heaviness in head is also felt by the patient suffering from Trapezius myalgia. Acute or chronic neck-shoulder pain is the hallmark of this condition. Trapezius Myalgia is a symptom of an underlying illness rather than a medical disorder or disease. The pain in the muscle usually lasts for few days or it can be even longer.<sup>1</sup> The presence of spasm in upper trapezius muscle is shown by neck pain in the back of the neck and between the bases of the neck and the shoulder. Low-level movement of the upper trapezius, which is linked to head posture and is a common cause of discomfort and neck pain in people who work at a desk or drive for long periods of time, is often seen during sitting and standing. Neck pain is very common in upper fibers of the trapezius muscle.<sup>2</sup>

Many people even experience soreness of the neck muscles after prolong sitting in front of desk or computers. These complaints are now even common in the student population due to increased sitting in front of computers or screens. According to researches it has been confirmed that most common type of neck pain is due to tenderness of the muscle, that is, Myalgia. Generally, such musculoskeletal disorders of neck are usually influenced by prolonged static work posture which leads to few pathophysiological changes in the upper trapezius. Due to physiological changes in the muscle, it leads to elevated anaerobic metabolism and fatigue due to repetitive work.<sup>3</sup> Women are more affected than men, and the prevalence is highest. When the

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muscle spasm occurs it feels like tightness and is painful. Spasm leads to knots in the muscle called, trigger points. These trigger points are formed because the activity of muscle is continuously “on”. Since the muscles are not designed for continuous overload, these types of knots are formed, which leads to spasm. Trigger points can be located by palpation over the muscle. According to some reports, a “jump sign” is elicited when applied pressure on the trigger point.<sup>4</sup> In the past, several physiotherapy protocols have been promoted that include, rest, heat, ultrasound therapy, stretching, strengthening exercises. These techniques have shown to give temporary relief.<sup>5</sup>

Myofascial release technique is a soft tissue mobilization technique that is described as "the facilitation of mechanical, neural, and psychophysiological adaptive capacity as interfaced through the myofascial system." It works by calming tense muscles while also improving circulation and lymph drainage. It works by altering the viscoelasticity of connective tissue. It restores proper muscle alignment. After releasing the trigger point, slight stretching gives longer pain relief.<sup>6</sup> TENS (transcutaneous electrical nerve stimulation) has been researched and used to relieve a variety of pains and symptoms. It is a non-invasive method that generates a low-frequency alternating electrical current that acts on the sensory level by closing the spinal cord gates and releasing endorphins. In previous studies, TENS has been shown to effectively alleviate pain in cases of musculoskeletal pain, arthritic pain, low back pain, neuropathic pain, and postoperative pain.<sup>7</sup> TENS is more effective in reducing pain as it can directly block the C-fibers carrying pain.<sup>8</sup> According to few other studies it has been reported that application of TENS also improves motor function.

The Low frequency TENS (<10Hz) focuses more on treating chronic pain where as High frequency TENS (80-100Hz) is often used for acute pain as it stimulates the A-beta fibers.<sup>9</sup> To our best knowledge, no study has been done so far for effect of high TENS in trapezius myalgia in college going students.<sup>10</sup> Due to various working environments of the subjects in previous studies it is unclear whether the treatment by High frequency TENS is beneficial for

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physiotherapy students. Therefore, the aim of this study is to compare the effectiveness of myofascial release and high- frequency TENS for pain relief and functional improvement in subjects with trapezius myalgia.

### **AIM**

The aim of the study is to investigate and compare the effectiveness of myofascial release versus high-frequency TENS for pain relief and functional improvement in college students with Trapezius Myalgia.

### **METHODOLOGY-**

#### **Study setting-**

The study will be carried out in Musculoskeletal-Physiotherapy OPD of Ravi Nair Physiotherapy College, Sawangi (Meghe), Wardha after getting approval from Institutional Ethical Committee of Datta Meghe Institute Of medical sciences, Deemed to be university.

#### **Study design and sample size-**

The design of the study is cross sectional study enrolling 45 participants. The participants enrolled in this study will be randomized in 1:1 manner into Myofascial Release group (Group A) and High- Frequency TENS (Group B), for 4 weeks each. Before inclusion, the participants will be explained about objectives and approaches of the study, and written informed consent forms will be signed by them. The study schedule of enrollment, intervention and assessment of study (as recommended by standard protocol items: a recommendation for intervention trials (spirit)).

## **PARTICIPANTS-**

The inclusion criteria of participants are under-

1. Patients who are willing to participate.
2. Age group 18-25 years old
3. Both males and females
4. Those who complain of excess pain and stiffness of neck
5. Those who have tight upper trapezius muscle
6. Those who intend to participate in the study

Exclusion criteria for participants are under-

1. Those who are more than 25 years of age
2. Those who suffered from structural abnormalities like torticollis, scoliosis
3. Those who had any wound over the neck area
4. Those who had history of any upper limb surgery
5. Those who had history of referred pain.
6. Those who were healing from fractures
7. Those who had any skin disease over their back
8. Those who are registered in another clinical trial

## **PARTICIPANT TIMELINE-**

As study duration is of 6 months and intervention duration is 4 weeks so participant will be enrolled mostly during first 2-3 months of study so 4week intervention will be completed successfully. Assessment will be done on 1<sup>st</sup> day of visit and then at the end of 4<sup>th</sup> week of intervention. Participant will have to visit 5 days a week for 4 weeks for treatment.

## **RECRUITMENT-**

The health care practitioners working under DMIMSU are invited to refer the prospective patients to our Out-patient department (OPD). The patients will be systematically assessed for the eligibility in the study as per inclusion and exclusion criteria. After enrollment in the study participants will be randomized in one of the group A or B and accordingly will undergo the rehabilitation program for 4 weeks with intermediate assessments. Informed patient consent will be taken before allocation and after explaining the purpose of the study, procedure, prospective benefits and after effects of intervention.

## **IMPLEMENTATION**

Randomization will be supervised by the research coordinator and principal investigators. Participants will be asked to handpick a sealed group allocation for the recruitment into either group from the envelope.

## **BLINDING**

Tester(s) will be blinded to assign the subjects to the group. To ensure blinding, subjects will be mandated not to reveal any details of their treatment to the tester.

## **STUDY PROCEDURE**

The subjects will be divided in to 2 different groups and their demographic data will be collected. Each participant will undergo the measurement of cervical range of motion prior to starting the treatment.

**Group A:** The participants in this group will undergo Myofascial Release Technique for the trapezius muscle, 5-10 minutes per day for 4 days per week for 4 weeks. Deep Transverse friction will be given first which will be followed by myofascial stretching of the upper trapezius muscle, all together for around 10 minutes. It will include use of techniques such as thumb after thumb pattern, ulnar border of palm and forearm to apply pressure and glide medially towards the base of neck or towards upper scapular region. It will be followed by application of cold pack over the trapezius to reduce the chances of soreness of the muscle. Daily this same procedure will be performed on the subjects to get the desired results.

**Group B:** The participants in this group will receive High- frequency TENS. The frequency will be ranging between 80-100Hz and electrodes would be applied over the trapezius muscle in linear pattern. The participants in this group will undergo 10 minutes of application of TENS at a comfortable intensity able to induce contraction of the upper trapezius muscle for 4- 5 days per week for 4 weeks. This application will be followed daily so that we are able to find the desirable result on the subject.

## OUTCOMES-

Primary outcome measures-

- **Numerical Pain Rating Scale (NPRS)**, is a segmented numeric version of the visual analog scale (VAS) in which a respondent selects a whole number (0–10 integers) that best reflects the intensity of the patient’s pain. The 11-point numeric scale ranges from '0' representing one pain extreme (e.g., “no pain”) to '10' representing the other pain extreme (e.g., “pain as bad as you can imagine” or “worst pain imaginable”).<sup>11</sup>
  - **Neck disability index**, has been designed to give us information as to how the neck pain has affected the patient’s ability to manage in everyday life. The questionnaire has total 10 segments and total score is 50. For each segment highest possible score is
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5 and lowest 0 in which 0 means 'No pain' and 5 means 'Worst imaginable pain'. A higher score indicates more patient-rated disability. <sup>12</sup>

## **DATA COLLECTION AND MANAGEMENT**

### **Data collection**

The evaluation data will be obtained from a pre-established spreadsheet with variable baseline characteristics. Research data will be placed in a secure database. Non-electronic records, such as hard copies of assessment forms, signed informed consent, etc., will be stored safely in the study setting.

### **Data management**

Data collection and reporting will be carried out under the supervision of the principal investigators. The research reports must be carefully checked for accuracy. The Excel spreadsheet will be published at the conclusion of the study and given to the statistician for the required analysis. Checklist can be used to avoid lost data due to incorrect staff procedures.

### **RESULT –**

Successful completion of this study will provide best treatment strategy in care of patients with trapezius myalgia in order to give early pain relief and gain functional activities and functional range at cervical joint. This study will also be useful in the treatment in the healthcare environment, as it will indicate that both myofascial release and high-frequency TENS will be helpful in alleviating pain of the trapezius muscle. Once the study result is completed, data will be analyzed and it will be submitted in form of research paper.

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## **DISCUSSION –**

Myalgia is usually known as muscle ache or muscle pain. Myalgia can occur in any muscle. In Trapezius myalgia, the patient complaints of pain, stiffness and tightness of the upper trapezius muscle.<sup>13</sup> This study aims to evaluate and compare the effectiveness of myofascial release vs high- frequency TENS for pain relief and functional improvement in patients with trapezius myalgia. Myofascial release technique is a soft tissue mobilization technique that is described as the facilitation of mechanical, neural, and psychophysiological adaptive capacity as interfaced through the myofascial system.<sup>14</sup> It works by calming tense muscles while also improving circulation and lymph drainage. As per study conducted by Chaudhary et al., MFR was more effective in improving pain pressure threshold in upper trapezitis. Another study conducted by Parab in his experimental study for relieving upper trapezius spasm by application of myofascial release and cryo-stretching, found that myofascial release proved to be effective in improving range of motion as well as immediate pain relief in comparison to cryo-stretching.<sup>15</sup> In 2018, Daxa conducted a comparative study to evaluate the efficacy of ART and MFR on trapezius muscle pain due to spasm, the most commonly found musculoskeletal disorder on 13 participants where it was found that MFR helped to decrease pain fast and lengthen the fascia. Therefore, also increased flexibility and cervical ROM.<sup>16</sup> Battecha & Kamel in their study conducted on 28 females for myofascial pain syndrome concluded that the combination of microcurrent therapy with traditional exercises was effective in managing patients with myofascial pain syndrome.

TENS (transcutaneous electrical nerve stimulation) has been researched and used to relieve a variety of pains and symptoms. It is a non-invasive method that has been shown to effectively alleviate pain in cases of musculoskeletal pain, arthritic pain, low back pain, neuropathic pain, and postoperative pain.<sup>17</sup> According to few other studies it has been reported that application of TENS also improves motor function. According to study conducted by Acedo et al. in their investigation for Upper trapezius relaxation induced by TENS and interferential current found that using TENS for trapezius tightness showed early pain relief and slight relaxation to the

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muscle.<sup>18</sup> In conclusion, this research seeks to explore and compare the effect of MFR and High frequency TENS in subjects with trapezius myalgia. The major outcome measures of this study are Numerical Pain Rating Scale (NPRS) and Neck Disability Index (NDI). These scales will help in assessing pain intensity and functional improvement of the patient.

### **ETHICAL APPROVAL AND DISSEMINATION**

Ethical approval will be taken from institutional ethical committee. The DMIMS who will fund for research and the subjects who will be participating in the study can access the main findings of the research. After completion of data collection, statistical analysis a completion report will be formed and after review by institutional research cell will be send for publication.

### **PATIENT CONSENT**

Principal Investigator will obtain the informed consent from the patient and one of the relatives on a printed form with signature and given the proof of confidentiality.

### **Confidentiality**

The study program will be elaborated to the participant and one of his/her relative, and principal investigator will take personal information as a part of procedure. The consent form will include the confidentiality statement and signatures of the principal investigator, patient and 2 witnesses. If required to disclose some information for the study, consent will be obtained from the patient with complete assurance of his/her confidentiality.

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