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Effectiveness of Functional Magnetic Stimulation versus Conventional Physiotherapy in Myofascial Pain Syndrome of Upper Trapezius: Study Protocol for a Randomized Controlled Trial

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Abstract

Background

Myofascial pain syndrome (MPS) of the upper trapezius is a common musculoskeletal condition characterized by active myofascial trigger points (MTrPs), leading to pain, disability, and diminished quality of life. Traditional physiotherapy, despite its prevalence, frequently offers merely transient alleviation. Functional Magnetic Stimulation (FMS) is an innovative, non-invasive technique that elicits painless, repeated muscle contractions using pulsed electromagnetic fields, potentially targeting underlying pathology.

Objective

To evaluate the efficacy of Functional Magnetic Stimulation versus traditional physiotherapy in alleviating pain, enhancing cervical range of motion (ROM), and diminishing disability in patients with myofascial pain syndrome (MPS) of the upper trapezius.

Methods

This parallel-group, randomized controlled experiment enrolled 54 patients aged 18 to 45 years with active myofascial trigger points in the upper trapezius muscle. Participants were randomly allocated in a 1:1 ratio to undergo either FMS therapy (Group A) or Conventional physiotherapy (Group B). Interventions were administered thrice weekly for a duration of three weeks. The primary outcome was pain severity measured using the Visual Analogue Scale (VAS). Secondary objectives encompassed cervical range of motion assessed with a goniometer and disability evaluated using the Neck Disability Index (NDI). Evaluations were conducted at baseline and after three weeks by a blinded evaluator.

Conclusion

This study aims to provide protocol to evident the effectiveness of FMS relative to Conventional physiotherapy for the management of MPS. By overcoming the shortcomings of current therapies, FMS has the capacity to enhance patient outcomes in a timely and non-invasive fashion.

Trial registration:

The study is registered with the Clinical Trials Registry – India (CTRI/2024/05/067997).

Keywords: Functional Magnetic Stimulation, Myofascial Pain Syndrome, Trigger Points, Upper Trapezius, Randomized Controlled Trial

I. Introduction

Musculoskeletal diseases (MSDs) are a primary cause of global disability, profoundly impacting quality of life, healthcare costs, and productivity. The Global Burden of Disease study indicates that musculoskeletal disorders (MSDs) are the second leading cause of years lived with disability globally [1]. Neck pain is particularly widespread among young individuals and office workers who engage in prolonged computer use, exhibit sedentary behaviors, and maintain poor posture [2].

Myofascial pain syndrome (MPS) is a persistent musculoskeletal disorder defined by the existence of myofascial trigger points (MTrPs) inside tense bands of skeletal muscle. Active myofascial trigger points (MTrPs) elicit spontaneous and referred pain, while latent MTrPs induce pain solely upon probing. The upper trapezius muscle is often impacted, resulting in rigidity, limited cervical mobility, and diminished everyday performance [3].

The pathogenesis of MPS encompasses extended sarcomere contraction, ischemia, metabolic stress, peripheral sensitization, and central sensitization. Therapeutic modalities encompass pharmacological intervention, manual therapy, dry needling, ultrasound

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treatment, thermotherapy, and exercise. Nonetheless, these techniques frequently provide merely temporary alleviation, may be intrusive, or are inadequately accepted [4–6]. Traditional physiotherapy procedures, such as heat fomentation, stretching, ultrasound, and manual release, have shown restricted long-term effectiveness [7].

Functional Magnetic Stimulation (FMS) constitutes a viable treatment option. FMS use high-intensity, pulsed electromagnetic fields to elicit depolarization of peripheral nerves, leading to repetitive muscle contractions without discomfort or dermal contact. These contractions improve local circulation, diminish muscular rigidity, and mitigate metabolic load at the MTrPs [8–11]. Notwithstanding its use in neurological and musculoskeletal disorders, evidence supporting its efficacy in upper trapezius myofascial pain syndrome is limited.

Objectives

The main aim of this experiment is to assess the efficacy of FMS relative to traditional physiotherapy in alleviating pain intensity, enhancing cervical range of motion, and diminishing impairment in individuals with upper trapezius myofascial pain syndrome.

II. Methods

Study design

This research is a single-arm, parallel-group, randomized controlled trial conducted in compliance with the CONSORT principles. It has been prospectively registered with the Clinical Trials Registry of India (CTRI/2024/05/067997). Ethical approval was secured from the Institutional Ethics Committee, and the trial was executed in compliance with the Declaration of Helsinki (2013 revision).

Participants

Inclusion criteria:

• Age between 18 and 45 years

• Clinical diagnosis of upper trapezius myofascial pain syndrome according to Travell and Simons' criteria (taut band, hypersensitive trigger point, referral pain pattern, restricted range of motion, and reproduction of pain upon probing)

• Pain duration exceeding 3 months

• VAS score ranging from 3 to 10

•NDI score between 20 and 35

Exclusion criteria:

• History of cervical trauma or surgical intervention

• Cervical radiculopathy or other neurological conditions

• Psychiatric disorders, malignancies, or systemic illnesses

• Recent dry needling or injection treatments

• Pregnancy

• Contraindications to magnetic or electrotherapy (e.g., pacemaker, metallic implants)

Sample size

Considering the expected medium effect size, $\alpha = 0.05$, and power $(1–\beta) = 0.8$, a minimum of 54 participants (27 per group) was determined necessary to identify clinically significant differences between therapies.

Randomization and allocation concealment

Participants were randomly assigned (1:1) to either the FMS group or the traditional physiotherapy group via a computer-generated randomization process created by an independent researcher. The allocation was hidden within consecutively numbered, sealed opaque envelopes.

Blinding

Participant and therapist blinding is impracticable due to the distinct nature of interventions; however, assessor blinding and allocation concealment have been ensured to minimize potential bias. This approach aligns with ethical and practical considerations in physiotherapy-based intervention studies.

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Interventions

Experimental group (FMS)

Participants underwent therapy with the BTL-6000 Super Inductive System. The stimulation applicator was placed across the upper trapezius myofascial trigger point region while the patient is in a prone position just 2 cm above the skin contact. The intensity was established at 30–40% of maximal output, modified according to tolerance, with frequency customized for *Trigger Points*. Each session endured for 10 minutes, occurring three times weekly over a span of three weeks, totaling 9 sessions.

Control group (Conventional physiotherapy)

Participants engaged in a comprehensive physiotherapy protocol comprising 20 minutes of hot fomentation, gentle stretching of the trapezius within pain-free thresholds, and continuous-mode ultrasound (1 MHz, 1 W/cm² for 5 minutes) administered over myofascial trigger points (MTrPs). Each session will endure for roughly 30 minutes, occurring three times weekly over a span of three weeks.

Outcome measures

Primary outcome

Pain intensity measured by Visual Analogue Scale (VAS)

Secondary outcomes

Cervical ROM (flexion, extension, lateral flexion, rotation) measured with a universal goniometer. Neck Disability Index (NDI) for functional disability

Assessments were performed at baseline and after three weeks.

Data collection and management

Data was gathered utilizing standardized forms and input into a secure electronic database. Double data entering was utilized to reduce inaccuracies. Personal identifiers were eliminated to maintain confidentiality.

Statistical analysis

All analyses will be conducted using the intention-to-treat principle to preserve randomization benefits. Missing data will be managed through last observation carried forward (LOCF) imputation. Data will be analyzed using SPSS software, with statistical significance set at $p < 0.05$.

III. Discussion

The trial focuses primarily on short-term effects to determine feasibility and preliminary efficacy of Functional Magnetic Stimulation for myofascial pain syndrome. This short-term evaluation is intended to generate foundational evidence for future research exploring long-term outcomes and broader clinical applications. This protocol indicates a randomized controlled trial aimed at assessing the efficacy of Functional Magnetic Stimulation relative to traditional physiotherapy for the treatment of upper trapezius myofascial pain syndrome. The trial seeks to fill existing gaps in the literature by evaluating if FMS, a non-invasive and time-efficient method, can yield enhanced results in pain alleviation, cervical mobility, and disability enhancement. The results of this experiment have contributed to evidence-based practice and directed the incorporation of FMS into physiotherapy regimens.

Strength and Limitations of the Protocol

This protocol is methodologically stringent, employing randomisation, allocation concealment, and assessor blinding, utilising validated instruments such as the Visual Analogue Scale (VAS), Neck Disability Index (NDI), and goniometric cervical range of motion (ROM). Nonetheless, blinding of participants and therapists is impractical due to the inherent characteristics of the therapies, potentially leading to performance bias. The brief intervention duration and absence of long-term follow-up limit findings regarding sustained efficacy. The disparity in treatment durations among groups and the lack of a sham-FMS control may also affect outcomes. Psychosocial variables, including quality of life, were excluded, as the current study primarily seeks to determine clinical efficacy and feasibility. Subsequent research ought to incorporate extended follow-up periods (1–3 months), bigger participant cohorts, sham-FMS controls, and the inclusion of psychosocial or quality-of-life assessments to enhance generalisability and therapeutic significance.

Trial status

Recruitment commenced in May 2024 and completed in June 2024. At the time of manuscript submission, the study has been finalized; however, the results are not disclosed in this protocol study.

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Declarations

Ethics approval and consent to participate

Approved by the Student's Reserach Committee of School of Physiotherapy, Delhi Pharmaceutical Sciences and Research University. nformed consent in writing was obtained from all subjects.

Consent for publication

Not applicable.

Availability of data and materials

Data generated from this study will be available upon reasonable request.

Competing interests

The authors declare no competing interests.

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No external funding was received.

Authors' contributions

SM conceptualized the study and prepared the protocol. SJ provided methodological inputs and critical revision. Both authors approved the final version of the manuscript after proofreading.

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