Study Protocol and Statistical Analysis Plan

Document Title: Comparative Effects of Connective Tissue Massage and Physical Modalities Added to Cervical and Scapulothoracic Stabilization Exercises on Pain, Function, and Endurance in Individuals with Chronic Neck Pain

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Study Protocol

Study Design

This study is a double-blinded, randomized controlled trial involving 51 individuals diagnosed with non-specific neck pain. Participants are randomly assigned to three groups. Group 1 receives only exercises that focus on cervical and scapulothoracic stabilization. Group 2 receives the same exercises in addition to connective tissue massage. Group 3 receives the same exercises along with electrotherapy consisting of infrared therapy, continuous ultrasound, and TENS applied to the painful area.

Inclusion Criteria

- Participants will be between 18 and 65 years of age,
- They will present with non-specific chronic neck pain localized in the posterior cervical spine between the occipital region and the spinous process of the first thoracic vertebra,
- They will be able to cooperate with the assessments required in the study.

Exclusion Criteria

- Neck pain resulting from trauma within the last 6 months
- History of any surgical procedure related to a cervical spine disorder
- Clinical signs of cervical radiculopathy and/or myelopathy
- Inflammatory arthritis affecting the cervical spine
- Tumors or infections involving the cervical spine
- Vertebrobasilar artery insufficiency
- Neurological disorders (e.g., multiple sclerosis, Parkinson’s disease, syringomyelia)
- Congenital anomalies affecting the spine
- Systemic diseases (e.g., diabetes mellitus)
- Shoulder pathologies (e.g., tendinitis, bursitis, capsulitis)

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Interventions

Participants are randomly assigned to three groups. Group 1 receives only cervical and scapulothoracic stabilization exercises. Group 2 receives the same exercises in addition to connective tissue massage, starting from the primary regions and gradually extending to other areas. Group 3 receives the same exercises along with electrotherapy consisting of 20 minutes of infrared therapy, continuous ultrasound at 2 W/cm² applied for 7 minutes on each side, and 20 minutes of conventional TENS applied over the painful area.

Each exercise session lasts 50 minutes, including 10 minutes of warm-up, 30 minutes of stabilization exercises, and 10 minutes of cool-down. Stabilization exercises are individually selected from an exercise pool and progress according to the participants' needs. The exercises are delivered face-to-face twice a week for 8 weeks. Additionally, participants are provided with illustrated brochures and are instructed to perform the exercises at home for one hour every day.

Outcome Measures

After providing detailed information about the study and obtaining informed consent, the physical characteristics and demographic data of all participants are recorded. Neck pain is assessed using the Bournemouth Neck Questionnaire, while neck-related disability is evaluated with the Neck Disability Index. Endurance is measured using the Deep Cervical Flexor Test, and quality of life is assessed with the World Health Organization Quality of Life-BREF (WHOQOL-BREF). Cervical range of motion is measured using a universal goniometer. To evaluate scapular dyskinesis, the Lateral Scapular Slide Test (LSST) and the Scapular Dyskinesis Test (SDT) are performed. All participants complete the questionnaires at baseline and at the 8th week, and all measurements are conducted and recorded by physiotherapists.

Statistical Analysis Plan

Sample Size Calculation

The number of participants to be included in the study was determined using the G*Power 3.1 program, based on a similar reference study (Dusunceli, Y., Ozturk, C., Atamaz, F., Hepguler, S., & Durmaz, B. (2009). Efficacy of neck stabilization exercises for neck pain: a randomized controlled study. *Journal of Rehabilitation Medicine*, 41(8), 626–631). The sample size calculation was based on our primary outcome parameter, range of motion (ROM). Power analysis indicated that at least 24 participants would be required to achieve 95% power with a 95% confidence interval. Considering a 10% drop-out rate, the final sample size was determined to be 27 participants.

Statistical Analysis

To compare baseline and post-treatment outcomes, ANOVA or Student's t-test is used for parametric data, while the Kruskal–Wallis and Mann–Whitney U tests are applied for non-parametric data. When significant differences among the three groups are detected, one-way analysis of variance (ANOVA) is conducted to determine the source of the difference. For pairwise comparisons, the Bonferroni post-hoc test is employed. A p-value of <0.05 is considered statistically significant.