Study Protocol Cover Page

Document Title: Study Protocol

Study Official Title: The Effect of Manual Therapy on Pain, Disability and Quality of Life in Patients with Chronic Mechanical Neck Pain

NCT Number:

Date of Document: March 15, 2026

Sponsor/Institution: Istanbul Rumeli University

Confidentiality Statement: This document contains confidential information. Participants' names of personal identifiers are **not included**.

Brief Description: This study protocol describes a randomized, parallel-group interventional study designed to compare the effectiveness of conventional physical therapy alone and conventional physical therapy combined with manual therapy in individuals with chronic mechanical neck pain. Participants aged between 18 and 65 years, who have had neck pain for at least three months and a minimum Visual Analog Scale (VAS) score of 3, will be included in the study. A total of 30 participants who meet these inclusion criteria will be randomly assigned into two groups, with at least 15 participants in each group. A total of at least 30 participants who meet the inclusion criteria will be randomly assigned into two groups, with a minimum of 15 participants in each group.

Group 1 (control group) will receive only conventional physical therapy, while Group 2 (intervention group) will receive conventional physical therapy in addition to manual therapy. The treatment program will be applied twice a week for a total of 10 sessions.

Outcome measures will include pain intensity assessed by the Visual Analog Scale (VAS), functional disability using the Neck Disability Index (NDI), quality of life evaluated with the Short Form-36 (SF-36), cervical range of motion (ROM), and the Bournemouth Neck Pain Questionnaire. All participants will be evaluated before the first session and after the completion of the treatment program.

Statistical Cover Page

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Brief Description: This Statistical Analysis Plan outlines the methods that will be used to evaluate the outcomes of the study conducted in individuals with chronic mechanical neck pain. The primary and secondary outcome measures include pain intensity assessed by the Visual Analog Scale (VAS), functional status evaluated using the Neck Disability Index (NDI), quality of life measured by the Short Form-36 (SF-36), cervical range of motion (ROM), and the Bournemouth Neck Pain Questionnaire.

The study is designed as a randomized, parallel-group intervention. A total of 30 participants will be divided into two groups: conventional physical therapy (Group 1) and conventional physical therapy combined with manual therapy (Group 2). All participants will be assessed before the first session and after the completion of the 10th session.

Statistical analyses will be performed using appropriate software. The normality of data distribution will be assessed using the Shapiro–Wilk test. For within-group comparisons, paired sample t-tests will be used, while independent sample t-tests will be applied for between-group comparisons. A p-value of less than 0.05 ($p < 0.05$) will be considered statistically significant.