

Cover Page

Official Title:

Comparison of the Effects of Thoracic Manipulation and Classical Massage on Pain, Flexibility, and Sleep in Patients with Mechanical Back Pain

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STUDY PROTOCOL

1. Background and Objective

Mechanical back pain is a common musculoskeletal condition affecting quality of life, physical function, and sleep. Manual therapy techniques such as thoracic manipulation and classical massage are widely used in physiotherapy practice; however, their comparative effectiveness remains unclear.

Objective:

To compare the effects of thoracic manipulation and classical massage on pain, flexibility, and sleep quality in patients with mechanical back pain.

2. Study Design

- Study Type: Interventional
- Allocation: Randomized
- Model: Parallel Assignment
- Number of Arms: 2
- Primary Purpose: Treatment

3. Participants

Inclusion Criteria

- Aged between 18–65 years
- Mechanical back pain for at least 3 months
- Voluntary participation

Exclusion Criteria

- History of spinal surgery
- Neurological or systemic diseases
- Acute trauma
- Pregnancy

4. Sample Size

- Total: 60 participants
- Classical Massage Group: 30
- Thoracic Manipulation Group: 30

5. Interventions

Common Treatment (Both Groups)

- Hot pack: 20 minutes
- TENS: 20 minutes

Group 1: Classical Massage

- Frequency: 2 times/week for 4 weeks
- Region: Upper back
- Techniques:
 - General stroking (3 repetitions)
 - Stroking and kneading applied to erector spinae and trapezius muscles (3 repetitions each)
 - Final general stroking

Group 2: Thoracic Manipulation

- Frequency: 1 time/week for 4 weeks
- Region: T1–T12 vertebrae
- Techniques:
 - Bilateral hypothenar manipulation (prone)
 - Butterfly technique
 - Unilateral prone manipulation
 - Dog technique
 - Costotransverse manipulation
 - Upper and mid-thoracic manipulation techniques

6. Outcome Measures

Primary Outcome

- Pain intensity (Visual Analog Scale – VAS)

Secondary Outcomes

- Quality of life (SF-36)
- Sleep quality (Pittsburgh Sleep Quality Index – PSQI)
- Postural assessment (New York Posture Analysis)
- Flexibility tests:
 - Sit-and-reach
 - Trunk extension
 - Right and left lateral flexion
- Muscle strength and endurance tests

7. Assessment Timeline

- Baseline (Pre-treatment)
- Post-treatment (4 weeks)

8. Ethical Considerations

- Informed consent obtained from all participants
- Study conducted in accordance with the Declaration of Helsinki
- Approved by the relevant Ethics Committee

STATISTICAL ANALYSIS PLAN (SAP)

1. Software: Statistical analyses performed using SPSS

2. Data Analysis: Normality assessed using Shapiro-Wilk test

Within-group comparisons: Paired t-test (parametric data), Wilcoxon test (non-parametric data)

Between-group comparisons: Independent t-test (parametric data); Mann–Whitney U test (non-parametric data)

3. Significance Level: $p < 0.05$ considered statistically significant

4. Missing Data Handling: Analysis performed using available data; Missing data not imputed

5. Outcome Evaluation: Changes from baseline to post-treatment analyzed; Group differences evaluated based on change scores