Study Protocol and Statistical Analysis Plan

Official Title: Effects of Chiropractic Combined with Conventional Physiotherapy in Patients with Non-Specific Chronic Neck Pain: A Randomized Controlled Trial
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Background and Rationale

Chronic non-specific neck pain is a prevalent musculoskeletal condition that negatively affects daily activities, mobility, work productivity, and overall quality of life. Despite the widespread use of conventional physiotherapy modalities such as transcutaneous electrical nerve stimulation (TENS), superficial heat therapy, and massage, many patients continue to experience persistent symptoms.

Chiropractic interventions, particularly spinal manipulation techniques, have been increasingly used in the management of neck pain. However, evidence regarding the **additional benefit of combining chiropractic treatment with conventional physiotherapy** remains limited and inconclusive. Therefore, further randomized controlled trials are needed to clarify whether this combined approach provides superior clinical outcomes compared to physiotherapy alone.

Objective

The aim of this study is to investigate whether adding chiropractic treatment to conventional physiotherapy improves pain, function, mobility, muscle strength, and quality of life in individuals with chronic non-specific neck pain.

Hypothesis

- **Primary Hypothesis:**
  Participants receiving chiropractic treatment combined with conventional physiotherapy will demonstrate greater reductions in pain and disability compared to those receiving conventional physiotherapy alone.
- **Secondary Hypothesis:**
  The combined treatment group will show greater improvements in range of motion, muscle strength, and quality of life.

Study Design

This study is designed as a **prospective, randomized controlled trial** with two parallel groups.

- Allocation ratio: 1:1
- Blinding: Assessor-blinded (if applicable)
- Duration: Approximately 3–4 weeks

Participants

Sample Size

A total of **40 participants** aged between 20 and 65 years with chronic non-specific neck pain will be included.

Inclusion Criteria

- Age between 20–65 years
- Diagnosis of chronic non-specific neck pain (≥3 months)
- Ability to understand and follow instructions
- Voluntary participation

Exclusion Criteria

- History of cervical spine surgery
- Neurological deficits or radiculopathy
- Serious spinal pathology (e.g., tumor, fracture, infection)
- Rheumatologic or systemic diseases
- Contraindications to chiropractic treatment

Randomization

Participants will be randomly assigned into two groups using a computer-generated randomization sequence. Allocation concealment will be ensured using sealed opaque envelopes.

Interventions

Group 1: Conventional Physiotherapy

Participants will receive:

- Transcutaneous Electrical Nerve Stimulation (TENS)
- Superficial heat therapy
- Neck massage

Group 2: Conventional Physiotherapy + Chiropractic

Participants will receive:

- All conventional physiotherapy modalities listed above
- Additional chiropractic treatment (spinal manipulation techniques applied to the cervical region)

Treatment Protocol

- Frequency: 2 sessions per week
- Total sessions: 7 sessions
- Duration: Approximately 3–4 weeks

Outcome Measures

Assessments will be performed **before and after the intervention period**.

Primary Outcomes

- Pain intensity (Visual Analog Scale – VAS)

- Disability (Neck Disability Index – NDI)

Secondary Outcomes

- Cervical range of motion (goniometer or inclinometer)
- Neck muscle strength
- Quality of life (e.g., SF-36)

Statistical Analysis Plan (SAP)

Data Analysis Software

Statistical analyses will be performed using SPSS (version XX) or equivalent statistical software.

Descriptive Statistics

- Mean ± standard deviation (SD) for continuous variables
- Frequency (%) for categorical variables

Normality Testing

- Shapiro-Wilk test will be used to assess data distribution

Within-Group Comparisons

- Paired t-test (for normally distributed data)
- Wilcoxon signed-rank test (for non-normal data)

Between-Group Comparisons

- Independent samples t-test (parametric)
- Mann–Whitney U test (non-parametric)

Repeated Measures Analysis

- Two-way repeated measures ANOVA (Group × Time interaction)
  or
- Mixed-model analysis (preferred if missing data exists)

Effect Size

- Cohen's d will be calculated to determine the magnitude of treatment effects

Significance Level

- Statistical significance will be set at $p < 0.05$

Ethical Considerations

The study will be conducted in accordance with the Declaration of Helsinki. Ethical approval will be obtained from the relevant institutional ethics committee. All participants will provide written informed consent prior to participation.