1.Cover Page

OFFICIAL TITLE: The Effects of Mulligan Joint Mobilization Versus Instrument-Assisted Soft Tissue Mobilization (IASTM) on Pain Intensity, Cervical Awareness, and Functional Status in Individuals with Chronic Neck Pain: A Randomized Controlled Trial

NCT NUMBER:

DOCUMENT TYPE: Study Protocol and Statistical Analysis Plan (SAP)

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2. Study Protocol

A. Objective(s)

The primary objective of this study is to compare the efficacy of Mulligan joint mobilization and Instrument-Assisted Soft Tissue Mobilization (IASTM) on pain, cervical awareness, and functional status in patients with chronic neck pain.

B. Study Design

- **Study Type:** Interventional (Clinical Trial)
- **Allocation:** Randomized
- **Intervention Model:** Parallel Assignment
- **Masking:** Single Blind (Assessor)
- **Primary Purpose:** Treatment

C. Methods & Interventions

- **Mulligan Group (n=20):** Participants will receive Mulligan joint mobilization techniques (e.g., SNAGs) targeted at the cervical spine.
- **IASTM Group (n=20):** Participants will receive soft tissue mobilization using specialized instruments (e.g., Graston technique tools).
- **Dosage:** Both groups will receive 12 sessions (3 sessions per week for 4 weeks).

D. Eligibility Criteria

- **Inclusion:** Ages 18-65, chronic neck pain (≥3 months).
- **Exclusion:** Recent surgery, cervical fractures, malignancy, or neurological deficits.

3. Outcome Measures

Outcome Measure	Tool/Scale	Time Frame
Pain Intensity	Visual Analog Scale (VAS)	Baseline, Week 4
Cervical Awareness	Fremantle Neck Awareness Questionnaire (FNAQ)	Baseline, Week 4
Functional Status	Copenhagen Neck Functional Disability Scale (CNFDS)	Baseline, Week 4
ROM	Universal Inclinometer / Goniometer	Baseline, Week 4
Muscle Endurance	Deep Cervical Flexor Endurance Test	Baseline, Week 4
Quality of Life	SF-36 Health Survey	Baseline, Week 4
Depression Level	Beck Depression Inventory (BDI)	Baseline, Week 4

4. Statistical Analysis Plan (SAP)

A. Sample Size Calculation

A total of 40 participants (20 per group) were determined to provide adequate power based on previous literature regarding cervical mobilization effects.

B. Statistical Methods

- **Descriptive Statistics:** Mean, standard deviation, and percentages for demographic data.
- **Normality Test:** Shapiro-Wilk test will be used to assess the distribution of data.
- **Within-Group Analysis:** Paired Samples t-test (parametric) or Wilcoxon Signed-Rank test (non-parametric) to compare pre- and post-treatment results.
- **Between-Group Analysis:** Independent Samples t-test or Mann-Whitney U test to compare the effectiveness of Mulligan vs. IASTM.
- **Significance Level:** $p < 0.05$ will be considered statistically significant.
- **Software:** SPSS Version [Versiyon No] will be used for all analyses.