



YEDITEPE UNIVERSITY

STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

The Acute Influence of Proprioceptive Neuromuscular
Facilitation on Cervical Proprioception and Range of Motion.

Date: 25/02/2019

NCT Number:
NCT04045106

Prepared by:

Mohammad AL-Jallad

ISTANBUL/TURKEY

Study Summery

Title	The acute influence of Proprioceptive neuromuscular facilitation on cervical proprioception and range of motion.
Methodology	Randomized, controlled trial, double blinded study
Study Duration	The estimated time for participants recruitment, screening and protocol implantation is 20 days
Study Location	University Labs
Subjects	120 healthy subjects randomized to 3 arms: 2 treatment and 1 control Inclusion criteria: To determine if a participant is healthy a score of 5 or less on the neck disability index will be used, no history of cervical trauma, rheumatic diseases, whiplash syndrome, no history of surgeries to the neck, face and shoulders, no history of cancer, no history of systemic diseases, age of 18 or above and able to understand and follow instructions.
Assessment	Cervical Proprioception using cervical range of motion (CROM) instrument, Active Range of motion (AROM) using CROM instrument, Muscle strength using a myometer device.
Intervention	PNF Pattern: Dynamic of reversals technique, PNF stretching: contract-relax-antagonist contract (CRAC) technique, control group: ineffective passive ROM.
Statistical Methodology	Statistical analyses will be performed using SPSS software version 25. Descriptive analyses will be presented using means and standard deviations for continuous data and frequencies and percentages for categorical data. The variables investigated using Kolmogorov Smirnov test to determine whether or not they are normally distributed. Since the variables are normally distributed, ANOVA will be used to compare the means of the groups., Levene test will be used to assess homogeneity of variances. When an overall significance will be observed, pairwise post-hoc tests will be performed using Tukey's test. Since the variables are not normally distributed Kruskal-Wallis test will be used to compare the groups. The Mann-Whitney U test will be performed to test the significance of pairwise differences using Bonferroni correction to adjust for multiple comparisons. Since the variables are normally distributed, the effect of time change in measurements will be investigated by Repeated Measures ANOVA test. Greenhouse-Geisser correction will be used when sphericity assumption is violated. Since the variables are not normally distributed Friedman test will be used. The Wilcoxon test will be performed to test the significance of pairwise differences using Bonferroni correction to adjust for multiple comparisons. A 5% type-I error level was used to infer a statistical significance.

Background information:

Proprioception is the ability to sense the information raised from the musculoskeletal system regarding the movement and position of body part in space, there are many types of proprioceptors in the body such as skin, joint capsule and connective tissue but the largest contributors to joint position sense are the intermuscular receptors which are golgi tendon organs and muscle spindles.

The cervical region has high density of muscle spindles that allow a great precision of movement while also providing adequate proprioceptive information to control head position and movement and for eye-head coordination.

Proprioceptive neuromuscular facilitation (PNF) are synergistic pattern of movement with the emphasis of facilitating normal movement, the proposed mechanism for some types of PNF that they are reliant on the facilitation of golgi tendon organs and muscle spindles which are responsible for two reflexes 1. autogenic inhibition 2. Reciprocal inhibition, although there is conflicting evidence regarding the mechanisms of PNF the beneficial effects are well established on many conditions like range of motion, neuromuscular functions, lymphedema and many more.

Most of the studies that tested PNF on the cervical region measured range of motion, flexibility and strength. Studies conducted to influence cervical proprioception used multiple interventions such as head relocation practice, eye/head coordination exercises, muscle vibration, mental training, strength and motor control exercises.

Due to the importance of cervical proprioception and the lack of studies in literature, the Purpose of this study is to investigate the acute influence of proprioceptive neuromuscular facilitation on cervical proprioception, range of motion and strength.

Study Design: This is a double-blinded randomized controlled trial. Participants were not aware of their assigned group, also the assessor was blinded to group allocation.

Sample Size: The sample size was calculated by using G*Power 3.1.7 for Windows (G*Power©, University of Dusseldorf, Germany), by using f family test ANOVA repeated measures and between factors, with statistical power of 0.80 (1-B error Probability) and alpha error level probability of 0.05 and effect size of 0.25 with number of measurements being 2, which total to 120 participants.

Participants will be recruited from university campus by directly asking students from classes if they can volunteer by explaining that the trial will involve the cervical region, also mentioned that is one-time session that can take up to an hour. Participants then will be handed consent forms that included more details about the trial.

Inclusion Criteria:

- Neck disability index score of 5 or less
- Able to understand and follow instructions
- Above 18 years old

Exclusion Criteria:

- Cervical trauma
- History of cervical inter-vertebral disc pathology
- Rheumatic diseases
- Whiplash syndrome
- History of surgeries to the neck, face and shoulders
- History of systemic diseases

Randomization and Procedures Randomization done by a person external to the study. Participants that signed the consent form and meet the inclusion criteria were assigned a number which corresponded to one of the three groups. Participants were asked to enter a room where the assessor performed the first measurements, then participants were asked to go to a separate room where the treatment methods took place. The therapist corresponded the number of the participant to the randomization sheet and applied the assigned treatment. After that participants were asked to go back to the first room for the second measurement. Participants were asked not to make a comment to the assessor but they can direct any question to the therapist.

ASSESSMENT METHODS

Cervical Proprioception: The cervical proprioception will be done using cervical range of motion instrument (CROM, Performance Attainment Associates, Lindstrom, MN, USA) using the joint position accuracy method of proprioception assessment, the device is made of a plastic frame that rest over the head, nose and ears, with a strap to secure it, it has three inclinometers attached to the frame, one in the sagittal plane, the second in the frontal plane and the third in the horizontal plane, which makes able to measure all 6 directions of movement. This instrument was reliable and valid to assess cervical proprioception, the chosen target angle is 30 degrees.

Cervical proprioception was done for flexion, extension, right side bending, left side bending, right and left rotation.

Participants will be asked to sit and put on the CROM instrument, then they will be instructed to start moving their head to one of directions then the assessor will stop them at 30 degrees and tell them to feel the amount of movement and muscle tension, this will be repeated 3 times as a reference, then they will be asked to do the movement with the eyes closed until they reach the target angle, this will be repeated for 3 times, this will be done for each direction and the assessor will record the results.

Range of Motion and Muscle Strength Measurement:

Active Range of motion (AROM) will be measured using CROM instrument, the validity and reliability of CROM to assess ROM is well documented in the literature, AROM was taken for all movement directions.

Muscle strength will be measured using a myometer device (microFET2™ Hoggan Health Industries, Inc, West Jordan, Utah), cervical flexors, extensors, right and left rotators and right and left lateral flexors muscle strength will be measured.

Intervention Methods

As discussed earlier, participants were allocated to three groups, these are PNF pattern, PNF stretching and a control group.

PNF patterns will be performed using Dynamic of reversals technique which is characterized as active motion alternating from one direction (agonist) to the opposite (antagonist) without relaxing.

The cervical patterns consisted of 1- Cervical flexion with right rotation followed by extension with left rotation. 2- Cervical flexion with left rotation followed by extension with right rotation.

The participants will be asked to sit on a chair, the therapist will perform the pattern of movement himself then passively apply the pattern on the participant then ask the participant to perform the pattern, and the therapist will observe and correct the movement if it was done improperly. then participants will be told that the therapist will resist their movement, they will be instructed to keep breathing normally and to report any discomfort and/or pain. After mastering the pattern, the therapist will place one hand on the participant's mandibular and the other hand approximately between parietal and occipital bones to apply resistance throughout the ROM, each pattern will be performed for 3 sets of 10 repetitions with 1-2-minute rest between sets.

PNF stretching will be done using contract-relax-antagonist contract (CRAC) technique for cervical flexors, extensors, right and left lateral flexors, right rotators and left rotators. This will be done for 6 repetitions with hold for 6 seconds in a position of stretch and submaximal isometric contraction for 6 seconds, 1-2-minute rest will be given before changing the target muscle group.

Control Participants allocated to the control group will receive ineffective passive ROM for 10 repetitions for flexion, extension, right and left side bending and right and left rotation, it will be done from neutral position to the limit of motion without causing any stretch to the muscle.

Statistical Analysis Plan:

Statistical analyses will be performed using SPSS software version 25. Descriptive analyses will be presented using means and standard deviations for continuous data and frequencies and percentages for categorical data. The variables investigated using Kolmogorov Smirnov test to determine whether or not they are normally distributed. Since the variables are normally distributed, ANOVA will be used to compare the means of the groups., Levene test will be used to assess homogeneity of variances. When an overall significance will be observed, pairwise post-hoc tests will be performed using Tukey's test. Since the variables are not normally distributed Kruskal-Wallis test will be used to compare the groups. The Mann-Whitney U test will be performed to test the significance of pairwise differences using Bonferroni correction to adjust for multiple comparisons. Since the variables are normally distributed, the effect of time change in measurements will be investigated by Repeated Measures ANOVA test. Greenhouse-Geisser correction will be used when sphericity assumption is violated. Since the variables are not normally distributed Friedman test will be used. The Wilcoxon test will be performed to test the significance of pairwise differences using Bonferroni correction to adjust for multiple comparisons. A 5% type-I error level was used to infer a statistical significance.