STUDY PROTOCOL PLAN AND STADISTICAL ANALYSIS PLAN (SAP)

UNIVERSITY CEU CARDENAL HERRERA

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TITLE: IMMEDIATE EFFECT OF SUBOCCIPITAL INHIBITION TECHNIC ON POSTURAL BALANCE: STABILOMETRIC STUDY.

Research and Ethics Committee of Cardenal Herrera CEU University

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STUDY PROTOCOL PLAN

1. OBJECTIVES

The objectives of our study are the following:

General:

- Check whether the technique of suboccipital inhibition influences suboccipital rachis proprioceptivity enough to modify postural balance.

Specific:

- Evaluate immediate changes in the oscillation of the center of gravity when standing after the suboccipital inhibition technique.

- Check the variation of the Romberg coefficient after the suboccipital inhibition technique.

2. STUDY DESIGN

A randomized controlled clinical trial of an explanatory, single-blind, blind appraiser strategy will be conducted (no relationship between evaluator and auditor). The subject will not know his group of belonging and, to strengthen his blinding, will not know how many measurements will be made. Participation in the study is free. The evaluation will be carried out before and immediately after the intervention.

All participants will be informed of the purpose of the study through an information document prepared for this purpose and will be clarified any doubts that may arise. After answering as many questions as necessary, the subject must sign the informed consent document to be part of the study. The principles of the Declaration of Helsinki (2004) will be respected at all times. The data collected will be treated confidentially by applying the current legislation on the protection of personal data (Organic Law 15/1999 of December 13, Protection of Personal Data) and / or any other applicable.

This study has been admitted by the Research and Ethics Committee of Cardenal Herrera CEU University Number CEI18/201

3. SUBJECTS OF STUDY

There is an increase in the prevalence of cervicalgia related to postural habits, new work practices and the use of electronic devices, traffic accidents and population aging. Cervical pain is very frequent with a point prevalence between 10-13%, appearing at some point in life up to 70% of the population. Occurs between 11-14% of sick leave. This situation justifies the feasibility of obtaining the sample required to carry out the study in an adequate time. The sample required for this project according to similar articles will be around 30 subjects per group.

The selection criteria of the sample in this study are as follows.

3.1. Inclusion criteria

The inclusion criteria will be: a) individuals who suffer neck pain for at least 3 months, b) Come to receive physiotherapy treatment at Clinica Osteomed (NRS: 8415-CV), Elche, Alicante, c) age between 18 and 65 years old, d) sign the informed consent.

3.2. Exclusion criteria

Exclusion criteria will be: a) suffering or having suffered pathologies of the postural control system (postural sensors, central nervous system or locomotor system), b) presenting deformities or orthopedic injuries in the lower limbs or rachis, d) presenting pain at the moment of study, e) present contraindications to the intervention under study, f) have received physiotherapy treatment in the last six months and g) have undergone surgical treatment of any kind.

Recruitment will be done after the first physiotherapy consultation. The physiotherapist will inform the patient of the characteristics of the study and, after checking their eligibility to participate in the study, will proceed to sign the informed consent.

4. INTERVENTION PROTOCOL

The intervention will be carried out by physiotherapists specialized in manual manipulative therapy, DO osteopaths, whose training and experience complies with the regulation of the provision of health care in osteopathy published in BOE of January 21, 2016 in the UNE-EN 16686 Standard: 2015 on "Provision of healthcare in osteopathy". The suboccipital inhibition technique is performed to release the myofascial restriction of the suboccipital region and normalize the proprioceptive afferents of the region. It is done with the patient in the supine position and the therapist sitting at the head of the bed with the elbows resting on its surface. The therapist palpates the cervical spinous processes

and slides the fingers upwards until contacting the posterior projection of the posterior arch of the atlas. Then, flexing the metacarpophalangeal at 90 degrees slowly raises the skull. The therapist's hands should remain together and the base of the skull should rest on his palms pressing with the index, middle and ring fingers of each hand in a sustained manner, but without causing pain. This pressure must be maintained during 4 minutes.

5. STUDY VARIABLES

5.1. Independent variables study object

The independent variables of the project are: a) belonging to the control or intervention group; and b) time, according to the timing of pre-intervention and post-intervention measurements. We also recorded as independent variables the general characteristics of the sample: age, BMI, sex, hours of weekly sports activity.

5.2. Dependent variables

The dependent variables of the study are Romberg index and stabilometric data with open eyes and closed eyes of the variables as follows:

- Mean of the oscillation on the X axis and on the Y axis.

- Length of the oscillation.

- Surface of the ellipse.

- Speed of the oscillation on the X axis and on the Y axis.

- Average speed of the oscillation.

6. STUDY GROUPS.

The sample will be divided into 2 groups: Intervention Group and Control Group. The suboccipital inhibition technic described will be applied to the intervention group. The control group will be given a superficial contact in the same area as the intervention, to rule out the exteroceptive effect associated with the therapist's contact. The subjects will be assigned to both groups through a computerized system of simple randomization.

7. EVALUATION.

The evaluation will be done at the Clinica Osteomed physiotherapy center located in Elche, where tools, space, evaluators and appropriately prepared interveners are available to carry out this project. The evaluation will be carried out in two moments: before the intervention and immediately after it. The time between the pre-intervention measurement and the intervention is less than 15 minutes. The time elapsed between the intervention and the post-intervention measurement will be less than 1 minute. For the evaluation a pressure platform will be used (Diagnostic Support SRL, model "Clinical MultiSensor", 4 sensors / cm2, 40 captures / second) and the data will be registered by the Milletrix software (Diagnostic Support V.1.0.0.26). The stabilometric record will be made with aligned heels in a comfortable position for the subject, looking forward at eye level on a wall 5 m from the subject. On both sides there will be two clear panels that will close a 3 m wide corridor. It will remain silent, constant temperature (20°-23°) and good luminosity (2000 Lux). The stabilometric record will have a duration of 52 seconds. The measurement will be made without footwear and the orders given to the subject will be protocolized so that they do not influence their postural attitude unequally.

Stabilometric data with open eyes and closed eyes of the variables, mean of the oscillation on the X axis and on the Y axis, length of the ball, surface of the ellipse, speed of the oscillation on the X axis and on the Y axis, average speed of the oscillation and the Romberg index.

8. STUDY SEQUENCE.

The study will be carried out in two adjoining rooms with enough space to offer freedom of movement to both the examiner and the subject of study. In one of them will be the evaluator, responsible for making the measurements and collect the pre-intervention and post-intervention values, using a stabilometric platform, a scale with stadiometer and a computer. The time that elapses between the execution of the technique and the start of the post-intervention measurement is, in all cases, less than one minute. In the other room, the intervener will be in charge of performing the randomization after the first measurement and performing the corresponding intervention. It will have a treatment table for the patient and a stool for the intervener. Between both rooms there are approximately eight meters without steps or unevenness.

A. Recruitment: Recruitment will be done after the first physiotherapy consultation. The

physiotherapist will inform the patient of the characteristics of the study and, after checking their eligibility to participate in the study, will proceed to sign the informed consent.

B. Evaluation pre-intervention. The subject of the study begins his participation in the evaluation room. The evaluator performs the pre-intervention evaluation. Following the protocol of the "Association Française de Posturologie" (AFP) the subject will be in a well-lit room (2000 Lux approximately), located on the platform with the heels separated 4 cm and with the tips of the feet forming a 30º angle. You will look forward to a fixed point located 5 meters above your eyes. On both sides, two light colored panels are placed. The width of the tunnel thus formed is 3 meters. In addition the room will be silent and the temperature will be constant between 20º and 23ºC so that the physiology of the subject is not altered to the point of feeling cold or sweating. We have decided to use this protocol because they are healthy subjects because, despite being an artificial position, we unify all the subjects in a position of certain instability because their heels are very close and their feet are symmetrical. Each foot is separated 15º of the sagittal plane. We will make the assessment with open eyes and closed eyes to determine the Romberg coefficient.

C. Randomization and intervention. The subjects are subjected at that moment to the randomization process. From that moment on, the sequence differs according to the group to which the individual has been assigned (control or intervention).

D. Evaluation post-intervention. A second stabilometric measurement is carried out immediately after the application of the technique, concluding the individual study.

9. PROVIDED BENEFITS

The technique proposed in this study should have an impact on the symptoms of instability and balance disorders associated with cervicalgia. The technique under study may be included in the protocols of conservative physiotherapy treatment for patients with cervicalgia and cervicogenic instability.

Statistical Analysis Plan (SAP)

Size Sample and Feasibility

The statistical program that we will use will be SPSS v.20. To determine the sample size, a pilot study will be conducted with the same methodology as the original study to a group of 10 subjects. These subjects will be assigned to the same group. This pilot study will provide us with the estimates of the mean and variance of the response variable, thus being able to calculate the appropriate sample size by determining a minimum power value of 80% (W> 80%) and a confidence level of 95% ($p < 0.05$).

The pilot sample will be part of the final sample to be studied if there are no changes in the protocol or in the variables to be measured.

For the descriptive analysis, the mean and the standard deviation will be calculated. To prove normality, the Kolmogorov-Smirnov test, or Shapiro-Wilk test, and for homoscedasticity the Levene test. To evaluate the pre-post intra-group differences, the t test will be used for related samples (if they are parametric) or the Mann-Whitney U test (if they are nonparametric). For the analysis of pre-post intergroup differences the ANOVA statistic will be used. The significance value is set at $p < 0.05$.