STUDY PROTOCOL PLAN AND STADISTICAL ANALYSIS PLAN (SAP)

UNIVERSITY CEU CARDENAL HERRERA

Principal investigator: Dr. Sergio Montero Navarro

TITLE: Analysis, Comparison and Evaluation of Cervical Range of Motion and Neck Pain After Deep Dry Needling and Superficial Dry Needling in the Upper Trapezius: A Randomised Controlled Trial

Research and Ethics Committee of CEU Cardenal Herrera University Number: CEI15/006

NCT ID (not yet assigned)

DATE: 12-4-2015

STUDY PROTOCOL PLAN

Objectives:

The objectives of our study have been the following:

General:

- Analyze, compare and evaluate changes in cervical range of motion and pain threshold pressure in the neck after performing the deep dry needling technique (DDN), the superficial dry needling technique (SDN) and a simulated dry needling technique in the gastrocnemius muscle (control group).

Specific:

- To evaluate the changes in the cervical range of motion (CROM) in homolateral and contralateral rotation, ipsilateral and contralateral inclination, flexion and extension at the cervical level. Myofascial trigger point (MTP) 1 of the upper trapezius.

- Determine changes in pain intensity after superficial dry needling technique (SDN) and deep dry needling (DDN).

- To compare the results of the technique of superficial dry needling (SDN), deep dry needling (DDN) and a simulated dry needling technique in the gastrocnemius muscle (control group).

Volunteers who want to participate in the study will read the general information of the study and sign the informed consent to participate in the study.

Once the informed consent has been read and delivered, the evaluator will check that they meet the inclusion criteria. After the data collection, a randomization (Epidat V4.0) of the selected subjects will be carried out to assign them to one of the intervention groups.

In the evaluation room, the evaluator, after taking the measurements of weight and height, will ask the subject to sit correctly on the chair, proceeding to locate the Myofascial trigger point (MTP) 1 of the upper trapezius, both right and left.

To locate the MTP 1, the palpation technique will be used, grasping the belly of the muscle between the thumb and the 2nd and 3rd fingers. The evaluator will press the fibers with a forward and backward movement to find the taut bands. Once the taut band is found longitudinally, the nodule and the point of greatest sensitivity to pressure will be located.

Once the MTP 1 is located, it will be marked with a dermal marker. Those subjects in whom the MTP 1 can not be located with precision, will be excluded from the study.

After having marked the MTP 1, the evaluator will make the subject the algometry in the MTP 1. 3 measurements will be taken with an interval of 20 seconds between measurement and measurement, and the average of the three measurements obtained will be calculated. After 5 minutes, the algometric measurement will be repeated to calculate statistically the error of the device in our study.

Next, the goniometer will be placed on the subjects and they will be instructed to do a right rotation movement, left rotation, right lateral flexion, left lateral flexion, flexion and extension with the back straight and hands placed on the thighs. Between movement and movement you will be asked to return to the starting position. After 5 minutes, the goniometric measurement sequence is repeated to calculate statistically the error of the device in our study.

Once the pre-intervention measurements have been made, the subject will go to the adjoining room to carry out the intervention.

The intervention sequence varied depending on the group to which the subject "Group intervention 1" (G1), "Group intervention 2" (G2) and "Control group" (G3) belonged.
The subject will be instructed to remove the shirt and lie down on the stretcher in the prone position. After one minute, the intervenor will proceed to perform the intervention according to the intervention group:

- "Intervention group 1" (G1): the superficial dry needling technique will be performed with a duration of nine minutes in the upper trapezius.

Initial position: Patient lying in prone position without shirt and with a contralateral cervical rotation of the side to be treated. The auditor is placed in a sitting position on a stool at the head of the stretcher.

Placement of hands: The auditor locates MTP 1 of the upper trapezius in the clamp of the side to be treated and, between his index and middle fingers with the thumb, he takes the MTP 1.

Technique: The inspector, with gloves, disinfects the area to be treated with 70º alcohol. Once the alcohol is applied, the interventor places the needle in the MTP 1, with the guide tube resting on the skin of the patient. The interventor holds the guide tube between the index and middle fingers, tap the needle with the index finger of the other hand to insert the needle into the skin. Once the needle is inserted at the subcutaneous level, the auditor removes the guide tube and rotates the needle until resistance to rotation is felt. After waiting for three minutes, the controller returns to rotate the needle until he notices a new resistance stop. This sequence is repeated a total of three times (nine minutes). Once the three stimuli have been made, the intervenor proceeds to withdraw the needle. Next, hemostasis is performed in the area. Once this hemostasis is completed, the patient is incorporated and dressed.

- "Intervention group 2" (G2): the deep dry needling technique will be performed with a duration of less than one minute in the upper trapezius.

Initial position: Patient lying in prone position without shirt and with a contralateral cervical rotation of the side to be treated. The auditor is placed in a sitting position on a stool at the head of the stretcher.

Placement of hands: The auditor locates the MTP 1 of the upper trapezius in the clamp of the side to be treated and, between his index and middle fingers with the thumb, he takes the MTP 1.

Technique: The inspector, with gloves, disinfects the area to be treated with 70º alcohol. Once the alcohol is applied, the intervenor locates and takes the MTP 1

and places the needle in the MTP 1 with the guide tube resting on the skin of the patient. The inspector holds the guide tube between the index and middle fingers, lightly touch the needle with the index finger of the other hand to insert the needle perpendicularly into the skin, directing it towards the inspector's thumb. Once the needle is inserted subcutaneously, the guide tube is removed. The controller deepens the needle to MTP 1, and makes fast inputs and outputs into the MTP. The rapid exit is made to the subcutaneous cellular tissue, outside the muscle, but not outside the skin. Next, hemostasis is performed in the area. Once this hemostasis is completed, the patient is incorporated and dressed.

- "Control group (G3)": the simulated dry puncture technique will be performed in the gastrocnemius muscle.

Initial position: Patient in prone position on the stretcher, with his head placed in the hollow of the stretcher. The intervener is placed in front feint, on the homolateral side of the side to intervencion.

Technique: The patient lies on the stretcher without the trousers. The interventor, with the guide tube, simulates the technique of puncture in the right twin of the subject. The comptroller cleans the area with 70º alcohol. Once the alcohol is applied, he performs the simulated puncture technique in a plane with his index and middle fingers with the guide tube. It is important that the subject has his head stuck in the hollow of the head of the stretcher throughout the technique to make a correct masking.

Next, a simulation of hemostasis is performed in the area. Once this simulation is finished, the patient is incorporated and dressed.

Once the intervention is done, the subject will return to the evaluation room to proceed to the evaluation immediately after the intervention (POSTINT), both algometric and goniometric. After these measurements, the subject will be summoned at the same time to return at 24 hours (POST24h), at 72 hours (POST72h) and at 7 days (POST7d) to perform the corresponding algometric and goniometric measurements.

This study will be carried out in two adjoining rooms, with a sufficient amplitude to offer freedom of movement, both to the evaluator and the auditor and the subject of the study.

In one of the rooms will be the evaluator to perform the measurements and collect the pre- and post-intervention values. In the adjoining room will be the controller, in charge of carrying out the corresponding intervention.

Between both rooms there are about eight meters of distance without steps or unevenness, and they will maintain an identical and constant temperature.

Statistical Analysis Plan (SAP)

To verify the correct randomization of the subjects to the intervention groups, a baseline homogeneity analysis of the pre-intervention response variables with the different explanatory variables will be performed. The statistical program that we will use will be SPSS v.20.

For the qualitative variables, double entry tables will be calculated and the Chi-Square test will be carried out ($\chi 2$). For the quantitative variables, mean values and standard deviation (SD) will be calculated and a variance analysis procedure (ANOVA) will be applied.

The pre-intervention response variables will also be evaluated in the three intervention groups, to check their homogeneity and correct masking of the evaluator, applying ANOVA procedures.

GENERAL STUDY INFORMATION AND INFORMED CONSENT

UNIVERSITY CEU CARDENAL HERRERA

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GENERAL STUDY INFORMATION

TITLE: **Analysis, Comparison and Evaluation of Cervical Range of Motion and Neck Pain After Deep Dry Needling and Superficial Dry Needling in the Upper Trapezius: A Randomised Controlled Trial**

Mr. Sergio Montero Navarro, Physiotherapist, principal investigator and researcher reports that:
The study in which will be part of joint mobility and pain at the cervical level. In this way we can contribute to promote the health status of people. A response at 24 hours, a third at 72 hours and a last at 7 days.

The tests performed are simple and in no case involve difficulty, fatigue, danger, injury, pain or adverse reaction. They will be held in the practice room of the CEU Cardenal Herrera University in Elche, specially prepared for the occasion and in the best conditions of safety and hygiene and always using approved material.

They will be carried out by collegiate physiotherapists in the School of Physiotherapists of the Valencian Community.

The general data of the subject will be collected (name, age, sex, physical variables and clinical history). The article must be sent with comfortable clothes The day that sea cited by the researcher, previous notice. Personal data is recognized in this study.

The personal data are confidential, apply to the protection of personal data (Organic Law 15/1999, December 13) and any other thing that may be applicable.

This study was approved by the Research and Ethics Committee of CEU Cardenal Herrera University (CEI15/006).

INFORMED CONSENT

Mr/Mrs..... with Number identification .... freely and voluntarily, I DECLARE:

That I have read the information contained in this document about the general information of the study.

I have been informed that all tests are simple to perform and do not produce harmful effects on health. They will be carried out in appropriate facilities and will be carried out by qualified and specialized personnel.

I have also been informed that, the data collected in this study will be treated confidentially, applying the current legislation on protection of personal data (Organic Law 15/1999, of December 13) and any other applicable.

Therefore, I give my consent and I authorize Mr. Sergio Montero Navarro, to carry out the detailed study in this document with the help of the necessary personnel with the appropriate qualification and specialization.

In Elche, to ..... of ..... of 201

Firm