STUDY PROTOCOL PLAN AND STADISTICAL ANALYSIS PLAN (SAP)

UNIVERSITY CEU CARDENAL HERRERA

Principal investigator: Dra. MªIsabel Rocha Ortiz

TITLE: Analysis, Evaluation and Comparison of Spirometric Values after the Application of the Diaphragm Muscle Stretch Technique and the Cervical Level Rotation Impulse Technique of C3-C4

Research and Ethics Committee of CEU Cardenal Herrera University Number: CEI13/01

NCT ID (not yet assigned)

DATE: 18-12-2015

STUDY PROTOCOL PLAN

Objectives:

The objectives of our study have been the following:

General:

- To evaluate the changes in the values of the simple spirometry after the application of the study techniques: muscle stretching technique of the diaphragm, rotation technique of the cervical level of C3-C4 and combined technique of both.

Specific:

- To determine the influence of the study techniques: diaphragm muscle stretching technique, rotation technique of the cervical level of C3-C4 and combined technique of both, on respiratory parameters measurable by simple spirometry.

- To compare the spirometric values obtained after applying the study techniques: diaphragm muscle stretch technique, cervical level rotation technique of C3-C4, combined technique of both and the control group.

- Analyze the different variables measured (age, sex, weight, height, sports practice and body mass index) in the effects of the applied treatment.

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.

All the subjects of the study will be tested for simple spirometry, before and after the intervention. To avoid the learning bias, the subjects that are part of the study will perform a minimum of three satisfactory forced expiratory maneuvers until reaching a variation of 150 ml of FVC and in FEV1 and a maximum of eight.

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.

The method of evaluation that we will use will be the simple spirometry for the study of the volumes and respiratory capacities, before and after the intervention. It will be performed in a sitting position, with the subject breathing through a disposable mouthpiece and with the nose occluded by a nose clip.

The spirometer we are going to use is the Datospir 120 (Sibelmed) model, classified as dry or flow sensor, with a turbine type transducer. This model was developed according to the standardization criteria of the Spanish Society of Pneumology and Thoracic Surgery (SEPAR), the American Thoracic Society (ATS) and the European Respiratory Society (ERS). It has a calibration program and has warning or warning notes on the compliance or not of the reproducibility criteria.

The material that we will use to perform spirometry will be located in a physical space located in a room adapted exclusively for this technique, which will allow a greater concentration on the part of the subject and the trained evaluator to perform the test. The material used will be the following: Datospir 120 Spirometer (Sibelmed), disposable and non-deformable cardboard nozzle, nose clip, table to locate the spirometry equipment, comfortable chair for the patient, scale and medical carver, allows to take the weight and size of the subject, tape measure to measure the contour of the thorax, thermometer for the ambient temperature.

The evaluator is the person who will perform the pre-intervention and post-intervention measurements. You will be trained in the correct use of the spirometer, as well as in the material to be used. It will be located in a room called the Evaluation Room, with the necessary material to perform spirometry and will follow the following protocol of action:

1. Volunteers who want to participate in the study will have to fill in the following annexes, in order to include them or exclude them from the study:

- The reading of the general information of the study and the signature of the informed consent.

- Anamnesis, collected in a proforma file, which will serve to corroborate the inclusion and exclusion criteria.

Once delivered and reviewed once all the annexes by the evaluator and be in accordance with the study methodology, will pass each subject to the Evaluation Room.

2. In the Evaluation Room, the subject will be instructed to perform three maneuvers of maximum inspiration followed by a forced expiration, until a maximum variation of 150 milliliters (ml) is obtained in the FVC and FEV1. If the subject fails to reach the acceptability of the maneuver, he will be allowed to make a maximum of eight maneuvers. In case of not reaching it and to cancel the learning bias, it will be excluded from the study.

3. Measurements of weight, height, BMI, chest contour will be taken and recorded.

4. The pre-intervention spirometric measurement will be performed. For this, the evaluator will indicate to the subject the steps to follow to perform the maneuver correctly:

- Sit with your back straight, to be comfortable, focused and calm to perform forced expiration. The evaluator will rest his hand on the subject's shoulder to prevent his trunk tilt forward in expiration.
- Put a clip on your nose.
- Tell you how the nozzle should be placed.
- It will mark when you have to breathe out.

Once the subject has correctly performed the steps of the evaluation protocol, he will go to the Intervention Room.

The interventor is the person who will perform the intervention techniques of the study. It will be located in a room called the Intervention Room, with the necessary material to perform these techniques, and will follow the following protocol of action. The sequence will differ according to the group to which the individual belongs (group "Intervention 1", group of "Intervention 2", group of "Intervention 3" and group "control")

To carry out the intervention in each of the cases, a hydraulic stretcher with two bodies, dimensions of 62 x188, model C-3723-J (Ecopostural) will be used. The subject will be instructed to lie down on the stretcher and the intervener will wait a minute before proceeding to perform the intervention that comes from the randomization.

- Group "intervention 1": the diaphragm muscle stretch technique will be performed. With a duration of 10 respiratory cycles.

- Group "intervention 2": the cervical level rotation technique of C3-C4 will be performed. With a duration of less than 30 seconds.

- Group "intervention 3": the muscle stretching techniques of the diaphragm and the rotation impulse of the cervical level of C3-C4 will be performed. With a duration of 10 respiratory cycles the first and a duration of less than 30 seconds the second.

- "Control" group: the simulation of any of the techniques of the intervention groups will be carried out, but innocuous in the response. With a duration of 1 minute.

Next, the subject will return to the evaluation room to proceed to the post-intervention spirometric analysis.

The study will be carried out in two adjoining rooms with sufficient amplitude to offer freedom of movement to both the examiner and the subject of study.

In a room there will be an evaluator, in charge of making the measurements and collecting the pre- and post-intervention values, with a simple spirometer and a computer.

In the other room there will be an auditor, who will carry out the randomization after the first measurement and carry out the corresponding intervention. It will have a stretcher for the patient and a stool for the auditor.

Between both rooms there are approximately eight meters of distance, without steps or unevenness.

The intervention techniques that will be carried out in the study, according to the intervention group, will be:

I. "Intervention 1" group: muscle stretching technique of the diaphragm in the supine position

Initial position: subject in the supine position, with a cushion under the head and neck, upper limbs resting on the stretcher along the body, the lower limbs flexed with the soles of the feet resting on the stretcher, leaving the same distance as the hips and with the knees bent 90 degrees.

Placement of the hands: the therapist stands at the patient's bedside, looking at the feet of the patient. The hands come in contact with the pisiform and the ulnar border of the triplanic fingers on the costal margin, encompassing the common cartilage of 7th, 8th, 9th and 10th ribs and points its arms towards the shoulder on the corresponding side.

Technique: tilting on his fingers, the inspector penetrates towards the inner zone of the costal cartilages and rib, and pulls using the weight of his body obliquely through each of his hands towards the shoulder of the corresponding side, coinciding with the inspirations of the subject; once comfortably accessed at the costal margin, it is pulled cephalad during inspiration and the costal opening is maintained during expiration. The subject is asked to take more air with the thorax than with the abdomen.
We will perform 10 consecutive repetitions per subject, a number that is considered sufficient to avoid adverse effects, such as dizziness, hyperventilation and / or fatigue in the subjects.

II. "Intervention 2" group: rotation technique of the cervical level of C3-C4.

Initial position: subject in the supine position. Therapist at the head of the stretcher, in double feint.

Placement of the hands: the corrective hand takes contact with the vertebra to be treated, on the side to be manipulated, after reduction of tissue tension: the second phalanx of the index finger, reinforced with the middle, contacts the lamina and articular process. The other hand makes a cranial shot placing the palm on the ear, the thumb at the height of the jaw, and the index and major fingers in front and behind respectively of the transverse on the opposite side to the one to be manipulated. The elbows are attached to the body.

Technique: to properly position the levers, with the thumbs the head is brought to the position of double chin and then placed with neutral flexion-extension until focusing on the level of manipulation, ipsilateral lateral flexion and contralateral rotation approximately 45 degrees.
The parameters are adjusted and the tensions accumulated before performing the specific impulse of contralateral rotation (thrust) that is carried out with the corrective hand.

III. "Intervention 3" group: muscle stretching technique of the diaphragm in the supine position and rotation technique of the cervical level of C3-C4.

The same initial position, hand placement and technique guidelines will be used, cited in each of the techniques performed in the "intervention 1" group and the "intervention 2" group.

At the end of the stipulated time according to the intervention technique. The subjects return to the evaluation room and the post-intervention spirometry measurement is immediately performed, concluding the study.

GENERAL STUDY INFORMATION AND INFORMED CONSENT

UNIVERSITY CEU CARDENAL HERRERA

Principal investigator: Dra. Mª Isabel Rocha Ortiz

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GENERAL STUDY INFORMATION

TITLE: Analysis, Evaluation and Comparison of Spirometric Values after the Application of the Diaphragm Muscle Stretch Technique and the Cervical Level Rotation Impulse Technique of C3-C4.

Dña. Mª Isabel Rocha Ortiz, Physiotherapist and researcher of the study reports that:

The study in which you are going to participate consists in performing a treatment to evaluate the improvement of the respiratory capacity and in this way, to be able to contribute to favoring the health status of the people. This study will allow us to link the scientific evidence with clinical practice, contributing to the treatments that are applied to improve the state of health, are supported scientifically and allow the professional to act correctly in the decision making and its subsequent intervention.

The tests to be performed are simple, and in no case involve difficulty, fatigue, danger, injury, pain or adverse reaction. They will be held in the Physiotherapy practice room of the CEU Cardenal Herrera University in Elche, specially prepared for the occasion and in optimal conditions of safety and hygiene and always using approved material. They will be carried out by collegiate physiotherapists in the Illustrious College of Physiotherapists of the Valencian Community.

General data of the subject will be collected (name, age, sex, physical variables and clinical history), the subject must be dressed in comfortable clothes on the day that is cited by the researcher, prior notice. The personal 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 that may be applicable.

This study was approved by the Research and Ethics Committee of CEU Cardenal Herrera University (CEI13/01).

INFORMED CONSENT

D./Dña.

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…. 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.

That I have been informed that all the tests are simple to perform, in a maximum of time of the day that they indicate me and do not produce harmful effects on health, which will be carried out in appropriate facilities and that will be carried out by qualified and specialized personnel.

I have also been informed that, the personal 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 that may be applicable.

That, therefore, I give my consent and I authorize Mrs. Mª Isabel Rocha Ortiz, 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 201

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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 used SPSS V.18.

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.