STUDY PROTOCOL PLAN AND STADISTICAL ANALYSIS PLAN (SAP)

UNIVERSITY CEU CARDENAL HERRERA

Principal investigator: Dr. Sergio Montero Navarro

TITLE: Stabilometric and baropodometric evaluation of osteopathic scaphoid tug manipulation

Research and Ethics Committee of CEU Cardenal Herrera University Number: CEEI22/322

NCT ID: [not yet assigned]

DATE: 10/13/2022

STUDY PROTOCOL PLAN

Objectives:

The objectives of our study have been the following:

General:

The main objective of this study was to evaluate, in healthy individuals, the stabilometric and baropodometric modifications recorded after an osteopathic tug manipulation of the scaphoid, neurophysiologically related to the static and postural control system of the body (exocaptor input) and biomechanically as a structure that communicates the body with the ground

Specific:

To evaluate by means of stabilometry the modifications in the variables of oscillation in X axis, oscillation in Y axis and ellipse area between the intervention group and the control group after the performance of an osteopathic scaphoid tug manipulation or a placebo technique respectively and to evaluate the results.

To assess the changes in the variables % weight load, bearing surface and maximum pressure in both feet by baropodometry between the intervention group and the control group after the application of a scaphoid tug manipulation or a placebo manoeuvre respectively and to compare the results.

To study and compare the results of the stabilometric and baropodometric variables obtained between the subgroups of the intervention group after the osteopathic tug manipulation of the scaphoid: audible and non-audible manipulation and to compare the results.

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.

The sequence of the study was as follows:

1. Information about the study to the subjects likely to participate.
2. Provision of the informed consent form to be read and signed by the patient (appendix I).
3. The evaluator will take the data for the clinical history.
4. The assessor will evaluate the mobility of the scaphoid of the right foot and will verify that it is in osteopathic external rotation dysfunction, if this dysfunction is not present, the subject will be excluded from the study.
5. The assessor shall collect data to obtain the independent variables of stabilometry and baropodometry by means of standardised recording on the measurement platform in a standardised room for this purpose.
6. The patient will go to an adjoining room with the auditor to carry out the randomisation process (random number generator) and thus classify the patient into the experimental or control group.
7. Implementation of the intervention: in the experimental group, the scaphoid tug technique will be performed. In the control group patients a sham technique will be applied.
8. The patient will return to the assessment room with the assessor for data collection to obtain the variables of stabilometry and baropodometry by standardised recording on the measurement platform, as was done previously.

9. Collection of data on computer support by means of a database.

Baropodometric and stabilometric assessment:

Stabilometric and baropodometric assessment was carried out using this sequence:

- The subject should be dressed in comfortable clothing and barefoot on the measuring platform.

- Upright position with arms relaxed.

- Placement of a wooden pattern for the positioning of the patient's feet, instructing him to place his feet against the edges of the wooden pattern and the heels subsequently contacting the guide (heel separation 2 cm and separation of 30º). Once positioned, the wooden pattern is removed.

- Stabilometric measurements and recordings: this shall be taken before the baropodometric recording, with a recording time of 51 seconds 2 tenths (standardised and consensual recording time).

- Measurement and baropodometric recording: this recording shall be performed after the stabilometric recording while maintaining the same posture.

The stabilometric evaluation will be carried out with the eyes open, as only the foot sensor will be evaluated in the study.

The stabilometric scan of this study will provide the following data:

- Oscillation about the X-axis.

- Y-axis oscillation.

- Area of the ellipse.

The static baropodometric scan of this study shall provide the following data:

- Area of support of the foot.

- Percentage of body load supported by each foot.

- Point of maximum plantar pressure.

Scaphoid mobility assessment.

Scaphoid mobility will be assessed by means of a manual mobility test, for which the eversion restriction of the first ray of the foot will be evaluated: patient lying supine on the stretcher, the assessor standing at the patient's feet, then takes the internal arch with one hand in a duckbill and with the other hand fixes the rearfoot at 90º, once the sockets are fixed he checks the direction of the restriction by performing a compression to test the talus-scaphoid and a lighter axial compression to test the first wedge-scaphoid joint. If there is restriction of scaphoid inversion or internal rotation movement, the test is positive, indicating that the scaphoid is in an osteopathic external rotation lesion.

Osteopathic tug manipulation of the scaphoid.

The aim of the scaphoid tug technique is to act on the scaphoid inferiority and external rotation lesion, releasing the scaphoid joint restriction in external rotation, correcting the possible flattening of the plantar vault and thus relaxing the possible hypertonia of the posterior tibialis.

The sequence of execution of the scaphoid tug technique shall be as follows: patient in the supine position, the intervener in a double feint at the patient's feet facing the patient's head, slightly oblique to the outside. The inner hand of the intervener makes contact with the pisiform through the hypothenar eminence and ulnar border of the hand over the scaphoid tubercle, the outer hand reinforces the contact. The thumbs are directed to the sole of the patient's foot. The parameters are sought by bringing the sole of the foot into eversion, thus bringing the scaphoid into internal rotation, i.e. in the direction of correction. To reduce the slack, the operator drops his body weight backwards while increasing the internal rotation parameter of the scaphoid. The

manipulation is performed by associating a rapid traction movement with an increase of the correction parameter towards scaphoid internal rotation.

Statistical Analysis Plan (SAP)

A descriptive and exploratory analysis of the variables of interest will be carried out in order to detect anomalous cases and to clean the database. The assumption of normality will be tested with the Shapiro-Wilks test in combination with an analysis of Q-Q and Q-Q normality plots without trend. The assumption of equality of variances will be tested with Levene's test. A repeated measures ANOVA model will be applied with the variable of interest as the within-subjects factor (three levels) and the group as the between-subjects factor (two levels). Bonferroni correction will be used for two-to-two comparisons. Effect size will be estimated with Cohen's d (1988) where values around 0.20 will be considered small effect size; around 0.50 moderate and 0.80 or higher, large. The statistical analysis software used will be IBM SPSS Statistics 24.0 (SPSS Inc. IBM Company, 2010) and a 95% confidence interval will be applied in all statistical tests.

GENERAL STUDY INFORMATION AND INFORMED CONSENT

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GENERAL STUDY INFORMATION

TITLE: **Stabilometric and baropodometric evaluation of osteopathic scaphoid tug manipulation**

Mr. Sergio Montero Navarro, Physiotherapist, principal investigator and researcher reports that:

The study focuses on the boropodometric and stabilometric modifications that occur immediately after an osteopathic scaphoid tug manipulation. In this way we can contribute to promoting people's state of health.

The tests performed are simple and in no case involve difficulty, fatigue, danger, injury, pain or adverse reaction. They will be carried out in the room of a registered clinic specially prepared for the occasion and in the best conditions of safety and hygiene and always with approved material.

They will be carried out by physiotherapists who are members of the Association of Physiotherapists of the Valencian Community.

The general data of the subject will be collected (name, age, sex, physical variables and clinical history). The subject should be sent in comfortable clothing. On the day that the researcher summons the subject, with prior notice. Personal data are acknowledged in this study.

Personal data are confidential, apply to the protection of personal data (Ley Orgánica 15/1999, de 13 de diciembre) and anything else that may be applicable.

This study was approved by the Research and Ethics Committee of the CEU Cardenal Herrera University.

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.

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