EFFECTS OF THERAPEUTIC EXERCISE PLUS CAPACITIVE-RESISTIVE RADIOFREQUENCY THERAPY AND PERCUTANEOUS ULTRASOUND-GUIDED NEUROMODULATION ON NON-SPECIFIC CHRONIC NECK PAIN.

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ABSTRACT.

Nowadays there is a great fluctuation regarding the definition of neck pain and the methodology to be used in neck pain research. This characteristic implies the difficulty to compare different studies and their results and conclusions. Defined as cervical syndrome, it encompasses all disorders of the musculoskeletal system that mainly involve pain. The primary objective of this study is to compare the effects of adding capacitive-resistive radiofrequency (RF) therapy and percutaneous ultrasound-guided neuromodulation (PNM) to therapeutic exercise (TE) in chronic non-specific neck pain (CNNP). This study is a randomized, controlled, parallel, double-blind, three-arm, double-blind treatment clinical trial. The different study variables will be measured immediately before the study and at 4, 8, 12 and 16 weeks respectively after completion of the study. The variables to be measured are visual analog scale for pain, range of cervical mobility and head posture in the sagittal and frontal plane, changes in the extent and location of pain, TAMPA 11 (TSK-11) kinesiophobia scale, cervical disability index and the pain catastrophism scale. The short and medium term changes produced by these therapies in subjects with CNNP will be studied. The sample will be randomly divided into three groups: group 1 ET plus RF, group 2 ET plus PNM, group 3 ET and placebo.

Key words: cervicalgia, neck pain, neuromodulation, radiofrequency, therapeutic exercise.

INTRODUCTION

Nowadays there is a great fluctuation regarding the definition of neck pain and on the methodology to be used in neck pain research. This characteristic implies the difficulty to compare different studies and their results and conclusions (1). Defined as a neck syndrome, it encompasses all disorders of the musculoskeletal system that are mainly associated with pain (2). Neck pain is described as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage in the neck region, beginning at the upper nuchal line and

continuing to the level of the scapular spine" (3). Non-specific neck pain is pain that does not show pathognomonic signs and symptoms (4). When the duration of symptoms is longer than 12 weeks of evolution, it acquires the value of chronicity and is called chronic non-specific neck pain (CNNP) (5). However it is defined, it is one of the top five chronic pain conditions in terms of prevalence and years lost to disability, although it receives a fraction of the research funding given to low back pain (6). Different studies have demonstrated changes in the behavior of the superficial and deep cervical musculature in patients with nonspecific neck pain, with greater activity of the superficial musculature such as anterior scalene and sternocleidomastoid as opposed to the deep flexor musculature which is diminished (7). Changes in the cross-sectional area of neck muscles in patients with chronic idiopathic neck pain have been shown to increase for all superficial flexor muscles except for the deepest flexor muscles, and decrease in almost all extensor muscles (8).As a methodology for the rehabilitation of patients with neck pain, therapeutic exercise (TE) is prescribed to activate the deep muscles and decrease the excess load on the superficial muscles. Deep cervical flexor training (DCF), a commonly used training method for patients with neck pain has been shown to improve cervical neuromuscular coordination (9). Low-load craniocervical flexion exercise has been effective in reducing and slowing the deterioration of the deep cervical flexor muscles in patients with chronic neck pain (10). On the other hand, the use of resistive capacitive radiofrequency (RF) therapy for the treatment of pain in different pathologies in recent years has been an interesting therapy to evaluate its results in combination with other treatment protocols and in isolation. The use of resistive capacitive radiofrequency therapy to treat postpartum perineal pain has been successful in reducing perineal discomfort when walking and in reducing postpartum paracetamol consumption (11). In a recent study on the analgesic effects of monopolar capacitive resistive monopolar radiofrequency in patients with chronic myofascial neck pain, the authors state that such therapy could have an effect in reducing pain intensity. Neck pain intensity improved immediately after one and eight sessions of monopolar capacitive resistive monopolar radiofrequency in the experimental group (12). Electrical stimulation of peripheral nerves is widely used in various medical settings. Due to recent technological advances, there has been increasing interest in the utility of peripheral nerve stimulation for pain control. Although the neuromodulatory effect of peripheral nerve stimulation was first explored in 1965, its principles share similarities with acupuncture and transcutaneous electrical nerve stimulation (TENS), which have long been used for pain control (13). Percutaneous neuromodulation (PNM) involves the use of electrical stimulation on a peripheral nerve by using a needle as an electrode to decrease pain and restore neuromuscular and nervous system functions. Peripheral nerve and muscle level neuromodulation (percutaneous neuromodulation [PNM]) consists of

percutaneous electrical stimulation of a peripheral nerve, along its pathway or in a muscle, through a puncture needle with low or medium frequency electrical current. Although the mechanism of action is not completely known, PNM involves the ascending and descending pathways, as well as the supraspinal regions of the central nervous system, regulating or modifying the electrical impulses transmitted through these pathways and thus inhibiting or exciting them. The main objective of PNM application is to provoke a motor and/or sensitive response that relieves pain and restores the normal functioning of the nervous system (14).

PRIMARY OBJECTIVE.

To compare the effects of adding capacitive-resistive radiofrequency (RF) therapy and percutaneous ultrasound-guided neuromodulation (PNM) to therapeutic exercise (TE) in chronic non-specific neck pain (CNNP).

SECONDARY OBJECTIVES.

To determine the changes in cervical pain in patients with CNNP through therapeutic exercise versus application of capacitive-resistive radiofrequency and percutaneous ultrasound-guided neuromodulation.

To evaluate the changes in head posture and craniocervical joint range in patients with CNNP with therapeutic exercise versus application of capacitive-resistive radiofrequency and ultrasound-guided percutaneous neuromodulation.

To assess the influence of kinesiophobia on the improvement induced by therapeutic exercise versus application of capacitive-resistive radiofrequency and ultrasound-guided percutaneous neuromodulation in patients with CNNP.

To assess changes in the extent of pain after therapeutic exercise versus application of capacitive-resistive radiofrequency and ultrasound-guided percutaneous neuromodulation in patients with CNNP.

To assess the changes in the disability experienced by the patient after therapeutic exercise versus application of capacitive-resistive radiofrequency and percutaneous ultrasound-guided neuromodulation in patients with CNNP.

METHODOLOGY

The different study variables will be measured immediately before the study, halfway through the study (4 weeks) at the end of the same (8 weeks) and 12 weeks after the end of the study. The variables to be measured are visual analog scale for pain, range of cervical mobility and head posture in the sagittal and frontal plane, changes in the extent and location of pain, TAMPA 11 (TSK-11) kinesiophobia scale, cervical disability index and the pain catastrophism scale. The short and medium term changes produced by these therapies in subjects with CNNP will be studied.

The sample will be randomly divided into three groups: group 1 ET plus RF, group 2 ET plus PNM, group 3 ET and placebo.

HYPOTHESIS:

Performing TE in combination with PNM and FR produces more beneficial effects with respect to pain, posture and disability in patients with CNNP.

TRIAL DESIGN.

This study is a randomized, controlled, parallel, parallel, double-blind, three-arm, randomized treatment clinical trial and is reported according to standard protocol elements.

SAMPLE SELECTION.

Individuals with CNNP will be recruited through a text message broadcast on social networks in the province of Almeria (Andalusia - Spain) and will be selected based on the eligibility criteria listed below. The study will be conducted at the Fisiosur Physiotherapy Clinic facilities in the town of Garrucha (Almeria).

INCLUSION CRITERIA.

- Age from 18 to 70 years.

- Current neck pain.

- Neck pain continued for at least the last 12 weeks (5).

EXCLUSION CRITERIA

- Neck pain radiating to upper limbs.

- Neck pain associated with vertigo.

- Osteoporosis.

- Psychological disorders.

- Vertebral fractures.

- Tumors.

- Metabolic diseases.

- Anterior neck surgery.

- Red flags (severe muscle spasm, involuntary weight loss).

- Physiotherapy treatment in the last 3 months.

INTERVENTIONS

Participants will only receive the assigned treatment; they may not combine treatment with medication or other physiotherapy treatment. Any interference with treatment will be grounds for exclusion.

Group 1. RESISTIVE-CAPACITIVE RADIOFREQUENCY THERAPY AND THERAPEUTIC EXERCISE.

The medical device to be used will be a Winback BACK1S. The data analysis will be independent of Winback and will be performed by Dr. Rodríguez Blanco, Cleofás. The device is a high frequency therapy device, registered and marketed exclusively by Winback, France and produced by Daeyang, South Korea, in accordance with 93/42/EEC under the number 1984-MDD-14- 108 314). The Back1S device used for the clinical study has 3 frequencies: 300KHz, 500KHz and 1MHz. Each frequency is supposed to allow targeting the depth of action: the lower the frequency, the deeper the action. Two frequencies (300 and 500 KHz) will be used during this study. The capacitive mode (CET) is an application mode that has a superficial action (2 to 3 cm) on soft tissues (high water content). The resistive (RET) is an application mode that allows to cross the total depth of the tissues and acts on all fibrous tissues (low water content). The dynamic function used within this protocol allows the device to automatically switch from 300 KHZ to 500 KHz frequency every 3 seconds (11). The device will be used with a power of 12 watts. The 60 mm diameter movable capacitive electrode and a 60 mm diameter movable resistive electrode will be used on the bilateral cervical paravertebral musculature from C0 to C7 and a planar electrode as a return electrode on the abdomen. The application will be performed as follows: with the patient in prone position; cream will be applied on the capacitive and resistive electrode and the electrical dose will be increased by moving the mobile electrode within the patient's tolerance level, while controlling the skin temperature tolerable for the patient. The therapy application time will be 10 minutes (5 minutes of application with the capacitive electrode and 5 minutes of application with the resistive electrode).

GROUP 2. THERAPY BY MEANS OF PERCUTANEOUS NEUROMODULATION AND THERAPEUTIC EXERCISE.

The subjects in the second group will receive therapy by means of percutaneous ultrasound-guided percutaneous neuromodulation of the spinal nerve bilaterally. Using an Esaote Mylab Gamma ultrasound machine with a linear musculoskeletal probe and the patient in the supine position, the spinal nerve will be located in the anteroinferior area of the upper trapezius bilaterally. The physiotherapist will previously disinfect the area to be treated with chlorhexidine and the puncture will

be performed with a 30X40mm acupuncture needle perpendicular to the right and left upper trapezius muscle, visualizing it in the ultrasound machine to avoid puncturing the pulmonary pleura. The needle tip will stop when it has contacted the epineurium of the accessory nerve (14)(15)(16). The needle will be the negative electrode. A second adhesive electrode will be placed 1 cm laterally to each of the negative electrodes. The parameters used will be set to low frequency (2 Hz) compensated symmetrical pulsed biphasic symmetrical pulsed current and a pulse width of 120 μs applied over a period of 15 minutes (17). The patient will be asked to indicate when the current intensity is tolerated and not painful.

GROUP 3. THERAPEUTIC EXERCISE PLUS PLACEBO.

In this group the subjects will receive 8 minutes of RF using the same protocols of patient positioning and use of electrodes and return plate as in group 1. In this case the application will be performed as follows: with the patient in prone position; cream will be applied on the capacitive and resistive electrode when appropriate, performing 4 minutes with the mobile capacitive electrode and 4 minutes with the mobile resistive electrode, but without increasing the intensity, so the intensity that the patient will receive will be 0.

THERAPEUTIC EXERCISE.

The three designated groups will perform the same TE sequence for 8 weeks. The physiotherapist will instruct the patient to perform them correctly. It is detailed below.

1st and 2nd WEEK: exercises 1 and 2.

41. Craneocervical flexion (CCF) in supine position with a towel on the back of the neck, the patient is asked to push the towel (3 series, 10 repetitions, 5s of contraction each repetition and 5s of rest between repetitions, with 30 s of rest between series) (18)(19).
42. Sitting CCF (3 sets, 10 repetitions, 5s of contraction each repetition and 5s of rest between repetitions, with 30s of rest between sets) (18) (19).

3rd AND 4th WEEK: exercises 1, 2, 3 and 4.

3. Co-contraction of deep and superficial neck flexors in supine position (10 repetitions, 10 seconds of contraction with 10 seconds of rest) (18)(19).

4. Sitting. Flexors, rotators and co-contraction inclinations. The patient will perform craneal flexion, while the physiotherapist asks the patient to bend, turn and look to the same side while the same patient opposes a resistance with the hand (10 repetitions, 10 s of contraction with 10 s of rest). (18) (19).

5th, 6th, 7th and 8th WEEK: exercises 1, 2, 3, 4 and 5.

5. Excentric for extensors. With the patient seated, he should perform a cervical extension, then he should perform a CCF and then finish doing a cervical flexion (10 repetitions) (18)(19).

OUTCOME MEASURES

1. VISUAL ANALOGUE SCALE (VAS) FOR PAIN

Subjects participating in the study will indicate the intensity of their pain by means of a 100 mm VAS. They should make a sign on a 100 mm horizontal line where they would place their pain, where 0 mm indicated “no pain” and 100 mm would be “worst pain imaginable” (20).

4 CERVICAL RANGE OF MOTION AND HEAD POSTURE IN THE SAGITTAL AND FRONTAL PLANE.

Measurement of posture

The PostureScreen® Mobile (PSM) application is a digital posturographic assessment tool to be used to perform a 3D postural examination. PSM has been established as a reliable and valid method to assess static posture (21)(22). The PSM calculates specific body angles and distances based on anatomical scanning and creates an output file containing values of postural variables and images of the participant that can be used to compare and analyze postural deviations. Participants will be instructed to wear appropriate clothing so that selected digital points can be measured and do not interfere with postural analysis and evaluation.

The following postural parameters will be evaluated (23):

SAGITAL PLANE.

- Craneovertebral angle. The acute angle formed between a straight line connecting the spinous process of C7 with the tragus of the ear, and the horizontal line passing through the spinous process of C7.

- Translation of the head anteriorly. Anteriorization on the sagittal axis (Appleton's line).

FRONTAL PLANE.

- Translation of the head laterally. Lateralization on the sagittal axis.

Range of cervical mobility in flexion, extension, rotation and lateroflexion.

- Measurement of active mobility by the patient while seated.

3. TAMPA 11 (TSK-11) KINESIOPHOBIA SCALE.

The Tampa Kinesiophobia Scale 11 (TSK-11) is an abbreviated version of the original 17-item questionnaire. The Tampa Scale for Kinesiophobia (TSK) is a widely used questionnaire designed to assess kinesiophobia, which is the fear of movement or re-injury. The TSK-11 is a shortened version of the original TSK consisting of 11 items (24).

4. CHANGES IN THE EXTENT AND LOCATION OF PAIN. PAIN EXTENT.

Changes in the extent and location of pain will be assessed using the Pain Extent application. It is a quick and easy-to-use tool compatible with commonly used operating systems and devices for assessing and monitoring the extent of pain in clinical and research settings (25).

5. NECK DISABILITY INDEX (NDI)

The NDI is a subject-specific functional status self-assessment instrument for subjects with neck pain with 10 items, including pain, self-care, weight gain, reading, headache, concentration, work, driving, sleep, and leisure. Each section is rated on a scale of 0 to 5, where 0 means “no pain” and 5 means “worst pain imaginable.” The points obtained are summed to a total score. The questionnaire is interpreted as a percentage. The disability categories for INDI are 0-8%, no disability; 10-28%, mild; 30-48%, moderate; 50-64%, severe; and 70-100%, complete (26,27).

6. PAIN CATASTROPHIZING SCALE (PCS)

Scale composed of thirteen items, each of them scoring from 0-4. The score will vary from 0 to 52. Higher scores will reflect higher levels of pain catastrophism. This scale shows acceptable psychometric characteristics (28).

PARTICIPANTS CHRONOLOGY

			STUDY PERIOD								
	ENROLMENT	ALLOCATION	POST- ALLOCATION								
TIMEPOINT	0 WEEK	1 WEEK	1 WEEK	2 WEEK	3 WEEK	4 WEEK	5 WEEK	6 WEEK	7 WEEK	8 WEEK	12 WEEK
ELIGIBILITY SCREEN	X										
INFORMED CONSENT	X										
CLINICAL EVALUATION AND INCLUSION-EXCLUSION CRITERIA	X										
ALLOCATION		X									
GRUPO 1			X	x	x	x	x	x	x	x	
GRUPO 2			X	x	x	x	x	x	x	x	
GRUPO 3			X	x	x	x	x	x	x	x	
DEMOGRAPHIC DATA	X										
VAS		X				X				X	X
POSTURAL HEAD AND NECK MOBILITY		X				X				X	X
TAMPA SCALE		X				X				X	X
PAIN EXTENT		X				X				X	X
NDI		X				X				X	X
PCS		X				X				X	X

SAMPLE SIZE CALCULATION.

The sample size will be calculated using the Granmo v.7.12 calculator, based on the minimum clinically important differences in VAS [20], and estimating an alpha risk of 5% (0.05), a beta risk of 10% (0.10), in a one-sided contrast, a standard deviation of 12% (0.12), a minimum difference to be detected of 10% (0.10), and a loss to follow-up rate of 10%, for which 34 subjects are required in each group, assuming three groups. If the loss-to-follow-up rate is greater than 10%, we will perform an intention-to-treat analysis. Finally, we will include 120 patients who will be divided into three groups, each group of at least 40 subjects, being able to exceed this value to assume possible loss to follow-up.

RANDOMIZATION.

The subjects will be divided into three groups by means of a balanced randomization performed with free software (htts://www.randomizer.org). The randomization sequence will only be performed by the principal investigator and the auditor.

BLINDING

The evaluator and study participants will be blinded throughout the process.

STATISTICAL ANALYSIS.

The statistical analysis will be carried out using IBM-SPSS Statistics 24 software. The normality test applied to all variables will be the Kolmogorov-Smirnov test. For the contrast of intragroup hypotheses, Student's t test for paired variables will be applied in the case of parametric distributions and Kruskal-Wallis H for nonparametric distributions. For between-group hypothesis testing, single-factor analysis of variance (ANOVA) will be used for parametric distributions and Kruskal-Wallis H for nonparametric distributions. Post hoc analysis will be obtained through Bonferroni contrast for parametric distributions and Mann-Whitney U for nonparametric distributions. Associations between pain (clinical improvement) and PS will be analyzed through Pearson's R or Spearman's rho. The confidence level used will be 95 % (0.05), and the power of the study will be 90 % (0.1).

DISCUSSION.

This study is a randomized controlled trial designed for the evaluation of pain changes in terms of pain intensity and extent of pain in non-specific neck pain. At the same time, changes in the patient's functional capacity, posture, degree of kinesiophobia and levels of catastrophism in the face of pain will be evaluated. For this purpose, the therapeutic tools to be used will be therapeutic exercise (9,10),

the application of capacitive-resistive radiofrequency therapy (11,12) and the percutaneous ultrasound-guided neuromodulation technique (13,14).

By means of this trial, we intend to determine the mechanisms that act on the variations in the patient's referral clinic after the use and combination of the therapeutic measures described. The effects of percutaneous neuromodulation and capacitive-resistive radiofrequency therapy on non-specific neck pain have never been previously investigated. Although these therapies are widely used in the clinical setting, there are no trials with relevant evidence to ensure the efficacy of these therapeutic treatments in combination with therapeutic exercise. Therefore, we cannot know if the positive and beneficial effects reported by the patient are a consequence of structural changes, central sensitization or psychosomatic variations as a consequence of the treatment and the physiotherapist's actions.

The double-blind randomized controlled clinical trial may contribute to increase the knowledge about the effects of the combination of these widely used therapeutic measures, as well as to open possible future lines of research in the treatment of non-specific neck pain.

TEST STATUS.

This is the first and final version of the protocol. Participants will be recruited between December 2024 and March 2025. Completion of the study is expected in July 2025.

KNOWLEDGE.

Not applicable.

ABREVIATIONS.

CNNP. Chronic non-specific neck pain.

TE. Therapeutic exercise.

DCF. Deep cervical flexor.

RF. Resistive capacitive radiofrequency.

TENS. Transcutaneous electrical nerve stimulation.

PNM. Percutaneous neuromodulation.

CCF. Craniocervical flexion.

VAS. Visual analog scale for pain.

PSM. PostureScreen® Mobile.

NDI. Neck Disability Index.

PCS. Pain catastrophizing scale.

AUTHORS' CONTRIBUTIONS.

Juan José González Gerez is the principal investigator, contributed to the concept, design and creation of the study, provided clinical experience and developed the manuscript. Cleofás Rodríguez Blanco is the project director, contributed to the development of the protocol, provided clinical experience, and is responsible for the design of the statistical procedures. Carlos Bernal Utrera contributed to the protocol in the methodological design and provided clinical experience. Ernesto Anarte Lazo contributed to the protocol statistical design and provided clinical experience. Raúl Romero del Rey contributed to protocol development and methodological design. Josefa M López de Haro provided clinical experience and contributed to the study design. All authors read and approved the final manuscript.

FUNDING.

This trial was carried out without external funding and its costs were borne by the sponsor and investigators.

AVAILABILITY OF DATA AND MATERIALS.

Not applicable.

ETHICAL APPROVAL AND CONSENT TO PARTICIPATE.

This study complies with the Helsinki guidelines for research in humans and has been approved by the Comité de Ética de la Investigación Biomédica de Andalucía (CCEIBA m). Only those participants who have received the study information from the principal investigator and have signed the informed consent form can be included in the study.

CONSENT FOR PUBLICATION

Not applicable.

COMPETING INTERESTS

The authors declare that they have no competing interests.

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