

Manual Therapy Versus Therapeutic Exercise in non-specific chronic neck pain: study protocol for a randomized controlled trial.

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Study protocol

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Abstract

• **Background:** Underlying mechanisms of non-specific chronic neck pain relapses are not clear, but it could be associated with a deficit and alteration of neck muscles proprioception that play a decisive role in cervical joint position, motor control of the head and postural stability. Numerous treatments for non-specific chronic neck pain have been described in the scientific literature. However, few studies analyze its influence on postural stability, since these alterations are not fully described, and various theories emerge about the reasons that cause it. Our main aim is analyze the differences in postural stability, pain, cervical disability and the relation between them produced by a treatment based on manual therapy and other based on therapeutic exercise. • **Methods:** The short-term and mid-term changes produced by different therapies on subjects with non-specific chronic neck pain will be studied. The sample will be randomly divided into three groups, manual therapy, therapeutic exercise and placebo. As dependent variables of the study, we will take: a) overall balance index, measured through a dynamic stabilometric platform; b) pain, based on the visual analog scale and the pressure pain threshold; c) cervical disability, through the cervical disability index. The findings will be analyzed statistically considering a 5% significance level ($p \leq 0.05$) • **Discussion:** Our study aims to provide knowledge about postural stability and its relationship with pain in subjects with non-specific chronic neck pain. Analyzing the results produced by different types of therapy will allow us to draw conclusions about the mechanisms that may elicit these alterations, structural or central mechanisms. • **Trial registration:** Brazilian Clinical Trial Registry, RBR-2vj7sw. Registered on 28 November 2018.

Background

Nonspecific neck pain is pain that does not show pathognomonic signs and symptoms, [1] when the duration of symptoms is greater than 12 weeks of evolution, it acquires the value of chronicity, being denominated non-specific chronic neck pain (NCNP). [2] It is a common disorder, which generates a great impact and socio-economic cost. [3]

Underlying mechanisms of NCNP relapses are not clear, but it could be associated with a deficit and alteration of the proprioception of the neck muscles that play a decisive role in the cervical joint position, motor control of the head and muscles. eyes, and postural stability (PS). [4-6]

Patients with NCNP usually have alterations in cervical proprioception and PS. May develop symptoms such as dizziness or vertigo. [7, 8] A recently published study shows that patients with NCNP suffer greater sensation of stunning and lack of proprioception than patients with benign paroxysmal vertigo. [9]

Numerous studies downplay the efficacy of manual therapy and therapeutic exercise for pain reduction, cervical disability and associated symptoms, such as dizziness. [10-12] However, there is less evidence of how these treatments, common in the clinical practice, influence PS. [13]

PS is highly influenced by the upper cervical spine and the suboccipital muscles, which is composed of up to 200 neuromuscular spindles per gram of muscle. [14, 15] This upper cervical segment is connected to the central nervous system (CNS), visual and vestibular apparatus and sympathetic nervous system. [16-19] In addition to cervical afferents through the cervico-ocular reflex (COR), the cervico-colic reflex (CCR) and the tonic neck reflex (TNR). CCR activates the cervical musculature in response to stretching, maintaining good head position; [20] COR through the vestibular reflex and the optokinetic reflex; [21] finally TNR added to the vestibulospinal reflex achieves the maintenance of the PS. [22]

The alteration of this proprioceptive complex is not completely defined. Various theories have tried to explain how this system can be altered. Some studies indicate that there is a proprioceptive alteration due to sustained exposure to pain that affects PS through the CNS, these changes may be due to changes in the cortical representation and modulation of the cervical afferent contribution. [23, 24] In addition, some authors begin to point out other psychobehavioral causes that could have a great influence on postural stability, such as anxiety, depression, or fear of movement. [5,6] We must bear in mind that these variables are present in a large number of patients with NCNP. [25, 26]

However, others relate the loss of PS to the dysfunction of the upper cervical spine and its musculature, changes in the cervical mechanoreceptors and the state of weakness of the musculature, [27-29] but not necessarily associated with traumatic events, since this type of alterations have been identified among subjects with NCNP without exposure to trauma. [29]

The area of dizziness of cervicogenic cause is quite unknown and there are several theories about its cause, and there is no consensus on the diagnostic criteria. [30] More research is needed about relationships between neck pain, postural stability and cervicogenic dizziness.

Primary Objective

The aim of our study is to compare two scientifically approved therapies for the NCNP, one of them with a greater influence on the structural component, and the other one, with a greater component on the central process, to observe differences in the PS of the subjects with NCNP.

Secondary Objective

Analyze the evolution of cervical pain and disability according to the treatment applied and the relationship with changes produced on postural stability.

Hypothesis

Experimental treatments have a greater beneficial effect on postural stability and pain of subjects with non-specific chronic neck pain than sham treatment. The improvement in postural stability is linked to an improvement in the subject's pain.

Trial Design:

Randomized, controlled, parallel, double-blind, three-arm clinical trial of treatment.

Methods/design

Sample Selection

Individuals with NCNP will be recruited through a text message broadcast on social networks in the city of Seville (Spain) and will be selected based on the eligibility criteria listed below. The study will take place in the facilities of the physiotherapy department of the University of Seville

Inclusion criteria

- Age 18–50 years
- Current neck pain
- Neck pain continued for at least the last twelve weeks. [2]

Exclusion criteria

- Irradiated neck pain
- Neck pain associated with vertigo
- Osteoporosis
- Psychological disorders
- Vertebral fractures
- Tumors
- Metabolic diseases
- Previous neck surgery
- Red Flags (Night pain, severe muscle spasm, loss of involuntary weight, symptom mismatch)
- Physiotherapeutic treatment continued in the last three months

Interventions

The participants can only receive the assigned treatment; they can not combine the treatment with drugs or other physiotherapeutic treatment. Any interference in the treatment will be grounds for exclusion.

Group 1: Manual Therapy

"Manual Therapy" protocol will be composed of three techniques based on scientific evidence for the treatment of neck pain [31-33]. These techniques represent a very close approximation to the treatment that is performed in the daily clinic, outside the research protocols.

This protocol will be applied in the three treatment sessions, one per week.

1. High Thoracic Manipulation on T4. [31]
2. Cervical Articular Mobilization (2 Hz, 2 minutes x 3 series). [32]
3. Suboccipital Muscle Inhibition (3 minutes). [34]

Group 2: Therapeutic Exercise

"Therapeutic Exercise" protocol: this protocol will be taught to patients in the first session and should be done once a day during the three weeks of treatment. It will be reinforced by the physiotherapist in each of the three individual sessions.

WEEK 1: Exercises 1 and 2.

1. Cranio-cervical flexion (CCF) in supine position with towel in the posterior area of the neck. (3 sets, 10 repetitions, 10 seconds of contraction each repetition with 10 seconds of rest).
2. CCF sitting. (3 sets, 10 repetitions, 10 seconds of contraction each repetition with 10 seconds of rest)

WEEK 2: Exercises 1, 2, 3 and 4.

3. Co-contraction of deep and superficial neck flexors in supine decubitus. (10 repetitions, 10 seconds of contraction with 10 seconds of rest).
4. Co-contraction flexors, rotators and inclines. Patients will performed cranial nerve flexion, while physiotherapist ask him to tilt, rotate and look towards the same side while he opposes a resistance with his hand. (10 repetitions, 10 seconds of contraction with 10 seconds of rest).

WEEK 3: Exercises 1, 2, 3, 4, 5 and 6.

5. Eccentric for extensors. With the patient seated, should perform cervical extension, then they must realice a cranio-cervical flexion and they finish doing a cervical flexion. (10 repetitions).
6. Eccentric for flexors. The patient will be in quadrupedal and neutral neck position, should perform neck flexion, then they must realice a cranio-cervical flexion, and maintaining that posture extend the neck and then finally lose the cranial-cervical flexion. (10 repetitions).

Group 3: Sham Treatment

"Control" protocol: Patients will be placed in the supine position, while the physiotherapist will lay his hands without therapeutic intention on the patient's neck for three minutes, the physiotherapist will simulate the technique of suboccipital inhibition [34], later by a means of a laser pointer off, they will be contacted without exerting pressure for 10 seconds. Patients assigned to the control group will receive treatment 1 or 2 after completing the study.

Outcomes Measures

- Neck Disability Index (NDI). The NDI is a self-assessment instrument of the specific functional status of subjects with neck pain with 10 elements that include pain, personal care, weight gain, reading, headache, concentration, work, driving, sleeping, and leisure. Each section is rated on a scale of 0 to 5, where 0 means "painless" and 5 means "the worst pain imaginable." The points obtained are added to a total score. The questionnaire was interpreted as a percentage. The disability categories for NDI are 0% -8%, without disability; 10% -28%, mild; 30% -48%, moderate; 50% -64%, serious; and 70% -100%, complete. [35, 36]
- Visual Analog Scale (VAS) for pain. The subjects participating in the study indicated the intensity of their pain by means of the EVA of 100mm, they had to signal in a horizontal line of 100mm where they would place their pain, being 0mm "no pain" and the 100mm would be "the worst pain imaginable". [37]
- Pressure Pain Threshold (PPT). The PPT was recorded in Newton / cm² using digital algometer (Force Ten™ -Model FDX, Wagner, Greenwich-USA) with a surface area of round tip of 1cm². The measurement was taken on the spinous process of vertebra C2, the evaluator gradually increasing the pressure until the patient indicated through a "Yes" when the pain or discomfort appeared. Three measurements were made, obtaining an average value of these three measurements for the statistical analysis. [38, 39]
- Overall Balance Index (OBI). We obtained this measurement through a dynamic stabilometric platform (Balance System™ SD, Biodex, New York-USA). The General Stability Test was applied in level of difficulty 4, with 1 being the highest and 8 the least difficulty. The platform is free in the anterior-posterior and medial-lateral axes, it allows obtaining the OBI through the deviations with respect to a zero point established before the test, with the platform stable. Two 20-second tests were performed, with one minute between each test, with the score of the second test that was chosen for the statistical analysis. The index is calculated through the anteroposterior and medial lateral relationship + standard deviation. [40, 41]

These variables will be measured in the pre-evaluation, first evaluation (week 2), second evaluation (week 4, short-term) and third evaluation (week 12, medium term). These evaluations will be carried out by an evaluator trained in them, the data will be stored in an excel document.

Participants' timeline

A brief Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) flow diagram is provided in Fig. 1, and a populated SPIRIT checklist is provided in Additional file 1.

TIMEPOINT	STUDY PERIOD							
	Enrolment	Allocation	Post-allocation (treatment)			Follow-Up (evaluations)		
	0 Week	1 week	1 Week	2 Week	3 Week	2 Week	4 Week	12 Week
ENROLMENT:								
Eligibility screen	X							
Informed consent	X							
<i>Clinical Evaluation and Inclusion-Exclusion Criteria</i>	X							
Allocation		X						
INTERVENTIONS:								
<i>Manual Therapy Protocol</i>			X	X	X			
<i>Therapeutic Exercise Protocol</i>			X	X	X			
<i>Sham Protocol</i>			X	X	X			
ASSESSMENTS:								
<i>Demographic Data</i>	X							
<i>Neck Disability Index</i>						X	X	X
<i>Visual Analog Scale</i>						X	X	X
<i>Pressure Pain Threshold</i>						X	X	X
<i>Overall Balance Index</i>						X	X	X

Sample Size Calculation

The sample size was calculated using the Granmo calculator v.7.12, based on the analysis of the variance of means, and estimating an alpha risk of 5% (0.05), a beta risk of 10% (0.10), in a unilateral contrast, a typical deviation of 10% (0.10), a minimum difference to detect of 9.8% (0.098) which is based as the minimum clinically important differences in OBI [42], and a rate of follow-up losses of 15%, for which 10 subjects are required in each group, assuming that there are three groups. Finally, we will include 66 patients who will be divided into three groups, each group of at least 20 subjects, being able to overcome this value to assume the possible loss of follow-up.

Randomization

Subjects will be divided into three groups by means of balanced randomization, carried out with free software (<http://www.randomized.com/>). The randomization sequence will only be done by the principal investigator and auditor.

Blinding

Evaluator and participants in the study will be blinded during the entire process.

Statistical Analysis

The statistical analysis will be carried out through the IBM-SPSS Statistics 24 software. The normality test applied to all the 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 non-parametric distributions. For the intergroup hypothesis contrast, one factor ANOVA will be used in the case of parametric distributions and Kruskal-Wallis H for nonparametric distributions. Post-Hoc analysis will be obtained through Bonferroni's contrast for parametric distributions and Mann-Whitney's U for nonparametric ones. Associations between pain (clinical improvement) and postural stability 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 article presents a detailed description of a randomized controlled trial designed to analyze the results in terms of pain, disability and postural stability of two types of treatments for non-specific chronic neck pain.

We intend to investigate a little-studied field such as postural stability in these subjects, and try to understand the mechanisms that may produce these alterations. We propose two types of treatments, one using manual therapy based on the structural influences of the neck and another based on the therapeutic exercise that exerts its effect through more neurophysiological mechanisms. Observing the effects of these two therapies we will try to analyze to gain a better understanding the mechanisms that cause postural instability in this type of subjects. Our results intend to present whether the provocative mechanisms have a more structural component, or instead, are caused by alterations produced at the level of the central nervous system by the sustained exposure of this to pain. In addition, we intend to establish relationships between clinical improvement in relation to pain with the improvement in PS of the subjects and analyze the differences depending on the treatment applied.

We have designed a randomized, controlled, double-blinded clinical trial, with the aim that our study could contribute to increase scientific knowledge on this matter, and could initiate new lines of future research.

Trial status

This is the first and definitive protocol version. Participants will be recruited between January-March 2019. Study completion is expected to be July 2019.

List Of Abbreviations

NCNP: Non-Specific Chronic Neck Pain

PS: Postural Stability

CCF: Cranio-Cervical Flexion

NDI: Neck Disability Index

VAS: Visual Analog Scale

PPT: Pressure Pain Threshold

OBI: Overall Balance Index

Declarations

Ethics approval and consent to participate

This study complies with the Helsinki guidelines for human research and it has been approved by the ethics committee of the University Hospital Virgen Macarena – Virgen del Rocío. The identification of each individual will remain concealed based on the ethical principles of confidentiality and privacy. All participants will receive an informed consent with information about all treatments and the randomization process that they will approve for participation in the study. Patients assigned to the control group will receive treatment 1 or 2 after completing the study.

Consent for publication

Not applicable.

Availability of data and material

Not applicable.

Competing interests

The authors declare that they have not competing interests.

Funding

This trial was conducted with no external funding and its costs have been assumed by researchers.

Authors' contributions

CRB is the director of the project, contributed to the protocol development, provided clinical expertise and he is responsible for designing statistical procedures. JJGG is the co-director of the project and contributed to the protocol development and provided clinical expertise. MSH contributed to the protocol in the methodological design and provided clinical expertise. MALO contributed to the protocol with the statistical design and provided clinical expertise. CBU is the principal investigator and has contributed to the concept and study design, provided clinical expertise and manuscript development. All authors read and approved the final manuscript.

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Figures

TIMEPOINT	STUDY PERIOD							
	Enrolment	Allocation	Post-allocation (treatment)			Follow-Up (evaluations)		
	0 Week	1 week	1 Week	2 Week	3 Week	2 Week	4 Week	12 Week
ENROLMENT:								
Eligibility screen	X							
Informed consent	X							
<i>Clinical Evaluation and Inclusion - Exclusion Criteria</i>	X							
Allocation		X						
INTERVENTIONS:								
<i>Manual Therapy Protocol</i>			X	X	X			
<i>Therapeutic Exercise Protocol</i>			X	X	X			
<i>Sham Protocol</i>			X	X	X			
ASSESSMENTS:								
<i>Demographic Data</i>	X							
<i>Neck Disability Index</i>						X	X	X
<i>Visual Analog Scale</i>						X	X	X
<i>Pressure Pain Threshold</i>						X	X	X
<i>Overall Balance Index</i>						X	X	X

Figure 1

Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) flow diagram

Supplementary Files

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