

PATIENT/SUBJECT INFORMATION DOCUMENT AND INFORMED CONSENT

Title of the research study:

**Effects of ultrasound-guided
percutaneous neuromodulation of the
accessory nerve and specific neck
exercises in patients with whiplash injury
in the subacute period: a randomised
clinical trial.**

9 June 2025

1) INFORMATION FOR THE SUBJECT/PATIENT PARTICIPATING IN THE STUDY

This study aims to evaluate the efficacy of different therapeutic strategies to improve cervical disability, neck mobility and reduce pain in patients with whiplash. One of the interventions, known as ultrasound-guided percutaneous neuromodulation (e-PNM), will consist of the use of needles (puncture technique), which will be performed by professionals specialised in rehabilitation. The intervention assigned to each participant will be determined randomly and will be performed by rehabilitation specialists.

INTERVENTIONS

Participants will be randomly assigned to one of the two study groups:

- Experimental group: Will receive one weekly session of e-PNM combined with specific supervised neck exercises for 3 weeks. ePMS will be performed before the exercises, using dry needling and an electrostimulator with parameters of 2 Hz to 250 microseconds for 20 minutes. The intervention on the accessory nerve will be performed on the side with the most pressure pain. This group will also receive an exercise protocol.
- Control group: Will perform the same exercise protocol as the experimental group, without receiving e-PNM treatments. The exercise protocol common to both groups will consist of two weekly sessions for 3 weeks, during which they will perform specific supervised neck exercises. The total duration of this protocol will be 40 minutes.

ASSESSMENTS

The evaluations will include questionnaires on cervical disability and visual scales on perceived pain, active neck joint mobility tests (flexion-extension mobility, rotations and tilts) and algometry measurement of the

trapezius muscles (a technique that uses an algometer to measure pressure pain thresholds, i.e., to quantify at what point the pressure exerted on the muscles begins to be perceived as painful. The assessments will be carried out before the interventions begin and there will be a total of 4 sessions. Each assessment session will last approximately 30 minutes and will take place at the following times:

- M0 (pre-intervention): Before the first intervention session with e-PNM.
- M1 (1 week post-intervention): At the start of the second treatment session with e-PNM.
- M2 (2 weeks post-intervention): At the start of the third treatment session with e-PNM.
- M3 (3 weeks post-intervention): One week after completing the treatment protocol.

BENEFITS OF THE STUDY

- To investigate the efficacy and safety of e-PNM of the accessory nerve in patients with whiplash injury.
- To contribute to improving the quality of life of patients with whiplash injury through new therapeutic approaches.
- To generate solid scientific evidence for e-PMS treatment of the accessory nerve in the management of whiplash in the subacute phase.
- To optimise rehabilitation resources by proposing more effective and cost-effective interventions.
- At the individual level, participants included in the study will receive free physiotherapy treatment aimed at improving their symptoms related to their subacute whiplash injury.

STUDY RISKS, PROCEDURES TO AVOID THEM AND CONTINGENCY PLAN

As this is a study based on an invasive intervention involving electrical stimulation, there are risks associated with the use of needles and electrical current, such as possible discomfort from the needle prick, possible discomfort during the application of electrical current, possible minimal bleeding from the puncture of smallcalibre vessels, possible



infection, or possible bruising after the intervention. The neck exercise protocol is very simple and safe; the only side effects that may occur are fatigue or dizziness.

However, it should be noted that the probability of the aforementioned risks occurring is minimal. Firstly, because it is a procedure that has been previously validated in studies with both pathological populations and healthy subjects. And secondly, because the researcher in charge of performing the procedure has the necessary knowledge to correctly apply all hygiene and safety measures (use of sterile gloves, probe covers and skin asepsis protocols). In addition, the procedure will be performed under ultrasound guidance, which increases its safety, and will always be supervised by a professional with experience in the use of invasive physiotherapy techniques, ensuring its correct execution. The neck exercise protocol will also always be supervised by a professional.

It should also be noted that if these risks do occur, such as pain, bruising, fatigue or dizziness, they will disappear spontaneously. Other risks, such as possible bleeding, will be stopped with the use of cotton wool, although these are so minor that they would also stop spontaneously.

PERSONAL DATA MANAGEMENT

All information collected will be treated confidentially and pseudonymised. Only the principal investigator will be aware of this pseudonymisation. This process will be carried out in an Excel document, in which the personal data of each participant will be collected and assigned a code, so that all information relating to each participant will subsequently be referenced with that identification code. This Excel document will be encrypted using the "7zip" system and the principal investigator will be responsible for its safekeeping.

The rest of the data obtained (non-personal data) will be collected in other documents, which will be headed by the participant's pseudonymisation code. This means that it will not be possible to associate the data with any specific participant.

Participants may withdraw at any time without having to justify their decision. For any questions or additional information, they may contact the research team using the details provided in this document.

2) INFORMED CONSENT.

I, [], with ID number [],
DECLARE THAT:

1. I have read and understood the information sheet for the study.
2. I have had the opportunity to ask questions.
3. My questions have been answered satisfactorily.
4. I have received sufficient information about the study and the tests to be performed and their procedures, as well as about the benefits and drawbacks of the process.
5. I understand that participation is voluntary and that I may withdraw from the study at any time without having to give any explanation and

without any repercussions. I have been informed of the contact person to whom I should report in order to do so.

6. I understand that I can withdraw from the research at any time (without having to give any explanation) and without this resulting in any prejudice or measures being taken against me. I have been informed of the contact person to do so. I have been informed that I have the right to choose what should be done with my data obtained so far (destruction or anonymisation of the sample, or preservation of research data obtained so far).

7. In accordance with the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, as well as other current and applicable regulations on the protection of personal data, I have been informed that my personal data, obtained by completing this form and resulting from my participation in the project, will be processed under the responsibility of the FUNDACIÓN UNIVERSITARIA SAN PABLO CEU (hereinafter, FUSP-CEU), for the purpose of managing my participation in this research project. In addition, I have been informed of the following aspects:

a. That the objective of this project is to analyse or predict aspects relating to my health

b. That the procedures indicated are legitimised by the consent I have given.

c. That my personal data, obtained by completing this form, as well as those resulting from my participation in the project, will be kept for the time necessary to carry out this research, which is estimated to be 4 months, and will subsequently be destroyed, without being kept without first being anonymised. In any case, they may not be transferred without my express consent, which I do not grant herein.

d. That I may contact the Data Protection Officer of FUSP-CEU by sending my request in writing to the postal address C/ Tutor nº 35 - 28008 Madrid or to the email address: dpd@ceu.es.

e. That, in accordance with the rights conferred on me by current data protection legislation, I may contact the competent Supervisory Authority



to submit any complaint I deem appropriate, and that I may also exercise my rights of access, rectification, limitation of processing, erasure, portability and opposition to the processing of my personal data and withdraw my consent to the processing thereof by sending my request to the researcher responsible at the contact address given in this document.

8. I agree that my written consent and other data may be made available to the research project in which I am participating and to the researcher responsible for it, Óscar Carvajal Fernández, but always respecting confidentiality and the guarantee that my data will not be made publicly available in such a way that I can be identified.

9. The data collected for this study will be included, together with that of other people participating in this study, in a personal database at CEU University, to which only researchers approved for this project Research Ethics Committee Subcommittee on Human Samples and Human Studies 5 will have access, all of whom are subject to the secrecy inherent in their profession or derived from a confidentiality agreement.

10. I voluntarily sign this information and consent form to express my desire to participate in this research study until I decide otherwise. By signing this consent form, I do not waive any of my rights. I will receive a copy of this document to keep and consult in the future.



Name and surname(s) of the patient/subject:

ID/Passport:

Signature:

Date:

Name and surname of legal representative, if applicable:

ID/Passport:

Signature:

Date:

Name and surname of the investigator:

ID number: 18091189X

Researcher's postal address: Lope de Vega 33-35, Los Manzanos, Logroño

Email: jllanosu01@gmail.com

Telephone: 667797244

Signature:

Date:

Approved by the study director (or principal investigator of the research study)

Signature: