

Official Title: Effects of Pain Neuroscience Education and Therapeutic Exercise on Pain, Catastrophizing, Kinesiophobia and Upper Limb Function in Patients With Non-specific Neck Pain.

Brief Title: Effects of Education and Exercise on Pain, Psychosocial Factors, and Upper Limb Function in Non-specific Neck Pain.

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PARTICIPANT INFORMATION SHEET

STUDY TITLE: “Effects of Pain Neuroscience Education and Therapeutic Exercise on Pain, Catastrophizing, Kinesiophobia and Upper Limb Function in Patients With Non-specific Neck Pain.”

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CENTRE: Miguel Hernández University of Elche

INTRODUCTION

We are writing to inform you about the research study in which you are invited to participate. This study has been approved by an Ethics Committee, in compliance with current legislation.

Our aim is to provide you with sufficient and appropriate information to enable you to decide whether or not you wish to participate in this study. We recommend that you read this fact sheet carefully and ask us any questions you may have after reading it. In addition, you can consult with the people you consider appropriate.

VOLUNTARY PARTICIPATION

It is important for you to know that your participation in this study is completely voluntary. You are free to decide not to participate or to change your mind and withdraw your consent at any time, without any detriment to yourself.

GENERAL DESCRIPTION OF THE STUDY

Education and exercise are two of the therapies currently being used as treatments for many musculoskeletal pathologies, both acute and chronic. Therapeutic exercise has significant effects on patients' recovery and well-being, improving strength, flexibility, mobility and joint stability, which contributes to a decrease in pain.

In terms of education, the idea is to provide pain education with the intention of improving the patient's understanding of their problem, facilitating a quicker return to activity and reducing the need for frequent medical attention. This technique, known as pain neuroscience education (PNE), is becoming increasingly important in the field of physiotherapy, since cognitive and emotional factors often have a major influence on the perception of pain, so an intervention on these factors could change the perceived pain.

The first hypothesis proposed suggests that patient education in pain neuroscience can reduce both kinesiophobia and catastrophizing. The second hypothesis seeks to determine whether tests, which require active movements, can reduce fear of movement and catastrophizing, thereby improving test results.

The subjects will be randomly classified into 3 groups: control group, exercise group and combined group. In the control group we will apply electrotherapy, as it is one of the most used therapies in the clinic nowadays. In the exercise group, functional tests will be carried out as exercise, with the aim of implementing active movement in the treatment. Meanwhile, in the combined group, in addition to the tests, we will carry out an education session in pain neuroscience, in order to study the joint effect of exercise and the addition of education.

BENEFITS AND RISKS OF PARTICIPATING IN THE STUDY

You will not receive any financial compensation for this. You will receive a treatment commonly used in physiotherapy clinics for the improvement of your pathology.

Adverse side risks are as follows:

- Slight increase in pain temporarily
- Exercise-related muscle soreness (stiffness)

Such events, which do not require medical or pharmacological intervention, resolve spontaneously and do not cause disability beyond mild discomfort.

If adverse events persist over time or are more severe than expected, the investigators should be notified. If necessary, the adverse side effects mentioned above will be treated with conservative therapies, typical of physiotherapy.

On the other hand, all subjects will be provided with a telephone number and an e-mail address where they can contact the project managers if they have any doubts or setbacks.

CONFIDENTIALITY

The processing, communication and transfer of the personal data of all participants will be carried out in accordance with the provisions of Organic Law 3/2018 of 5 December on the Protection of Personal Data and the guarantee of digital rights, as well as Regulation (EU) 2016/679 of the European Parliament.

The data will be collected in a research archive and will be used exclusively in the context of your participation in this study.

In accordance with data protection legislation, you have the right to access, rectify, oppose and delete your data. To exercise these rights, you should contact the study manager.

The data collected for the study will be identified by a code, and only the study researchers or their collaborators will be able to link this data to you. Therefore, your identity will not be disclosed to anyone, except in cases of medical emergency or legal requirement.

Access to your personal information will be restricted to the researcher/collaborators, health authorities (Spanish Agency for Medicines and Health Products), the Medical Research Ethics Committee and personnel authorised by the sponsor, when required to check the data and procedures of the study, but always maintaining the confidentiality of these in accordance with current legislation.

Only the data collected for the study will be transmitted to third parties and to other countries, and under no circumstances will it contain information that can directly identify you, such as name and surname, initials, address, etc. In the event of such a transfer, it will be for the same purposes of the study described and guaranteeing confidentiality.

OTHER RELEVANT INFORMATION

If you choose to revoke your consent to participate in this study, no new information will be added to the database, and you have the right to request the destruction of all identifiable samples previously retained to prevent further data analysis.

It is also important for you to know that you may be excluded from the study if the researchers deem it necessary to do so, either for safety reasons or if they determine that you are not complying with established procedures. In either case, you will be provided with an adequate explanation of the reasons for your exclusion from the study.

By signing the attached consent form, you agree to comply with the study procedures that have been explained to you.

Participant Consent Form.

STUDY TITLE: "Effects of Pain Neuroscience Education and Therapeutic Exercise on Pain, Catastrophizing, Kinesiophobia and Upper Limb Function in Patients With Non-specific Neck Pain."

I, (name and surname of the participant)

.....

- I have read and understood the information sheet I have been given about the study.
- I was able to ask questions about the study.
- I have received enough information about the study.
- I have spoken to:

.....

- I am aware of and assume the risks and/or consequences that may arise from my participation.

- I understand that I may withdraw from the study:

- Whenever I want.
- Without having to give explanations.
- Without this having repercussions on my physiotherapy care.

- In accordance with the provisions of Organic Law 3/2018, of 5 December, on the Protection of Personal Data and the guarantee of digital rights, and Regulation (EU) 2016/679 of the European Parliament, I declare that I have been informed of the existence of a file or processing of personal data, the purpose of the collection of this data and the recipients of the information.

- I freely give my consent to participate in the study.

Participant's signature

Signature of the investigator

Date: ____/____/____

Date: ____/____/____

Revocation of consent:

Mr./Mrs, with DNI..... I REVOKE the consent previously given for the carrying out of this procedure of my own free will.

Participant's signature

Date ____/____/____