01/05/2026

INFORMED CONSENT DOCUMENT AND CONFIDENTIALITY AGREEMENT

1.- INFORMATION FOR THE RESEARCH PARTICIPANT

The research project for which we request your participation is entitled:
"EFFECTIVENESS OF PAIN NEUROSCIENCE EDUCATION COMBINED WITH THERAPEUTIC EXERCISE IN PEOPLE WITH CHRONIC PAIN."

In order for you to participate in this study, your consent is required, as well as your understanding of the basic information necessary for such consent to be considered truly informed. Therefore, please read the following information carefully. If you have any questions, please ask them before signing this document, either personally or via telephone or email, to the principal investigator of the project. The principal investigator's contact details are also included in this document.

The basic information you should know is as follows:

a) Objective of the study:

The main objective is to evaluate the effectiveness of an intervention based on Pain Neuroscience Education and Therapeutic Exercise in people with chronic pain. The specific objectives are:

1. To evaluate the effectiveness of a Pain Neuroscience Education intervention combined with Therapeutic Exercise on pain, pain catastrophizing, and pain sensitization, as well as functionality, in people with chronic low back pain and fibromyalgia.
2. To compare the effects of a Pain Neuroscience Education intervention combined with Therapeutic Exercise on pain, pain catastrophizing, pain sensitization, and functionality according to the clinical condition, namely chronic low back pain and fibromyalgia.

b) Methodology to be used in the study, type of collaboration expected from you, and duration of participation:

The treatment will last 8 months, with therapeutic exercise sessions conducted 3 times per week. This program will include multimodal exercises, and each session will last approximately 45 minutes. In addition, educational activities lasting 20–45 minutes will take place twice per week, covering different topics aimed at understanding spinal biomechanics and pain mechanisms.

Participants will be assessed before the intervention (T1) and after the intervention (T2). Furthermore, to evaluate the durability of the effects, a follow-up assessment will be conducted four weeks after the intervention has ended (T3).

c) Available preventive, diagnostic, and/or therapeutic alternatives to those being investigated in this study:

Not applicable.

d) Possible discomforts and risks associated with participation in the study:

The Pain Neuroscience Education intervention is not associated with any risk. Regarding therapeutic exercise, although risks are minimal, musculoskeletal issues may occur (for example: muscle overload, stiffness, fatigue, and pain).

e) Measures to address adverse events:

If any of these symptoms occur, treatment will be stopped and resumed the following day.

f) Measures to ensure adequate compensation in the event that you suffer any harm:

In the event of any unexpected circumstance, medical and/or nursing support will be provided.

g) Expected benefits of the research:

This study is of interest to people with chronic pain, specifically individuals with chronic low back pain and fibromyalgia, as it aims to investigate the effects of an intervention based on Pain Neuroscience Education combined with Therapeutic Exercise. Potential benefits include pain reduction and reduction of its consequences, as well as improved spinal functionality.

h) Consequences of non-participation:

You are not obliged to participate in this study. If you choose not to participate, this will not affect your right to healthcare. Furthermore, the relationship with the people who invited you to participate will remain equally cordial and attentive regardless of whether you decide to participate.

i) Possibility of withdrawal at any time and consequences:

You may withdraw from the project at any time by signing the consent withdrawal form included at the end of this document. Your withdrawal will not have any negative consequences for you and will be accepted without issue by the research team.

j) Who has funded the study?

This study has not received funding.

k) Which institution is conducting the study?

The study is being conducted at the Universitat de València.

l) Participation free of charge:

Your participation will be free of charge.

m) Expected subsequent use of the results:

(Indicate whether the results will be used for teaching, research, and/or scientific publication purposes.)

n) Research team:

The research team for this project is composed of two undergraduate Physiotherapy students and the following members of the Department of Physiotherapy at the Universitat de València, belonging to the Clinical Biomechanics Research Unit (UBIC group):

- M. Pilar Serra Añó, Full Professor
- Marta Inglés de la Torre, Associate Professor
- Elena Muñoz Gómez, Assistant Professor
- Sara Mollà Casanova, Assistant Professor
- Noemí Moreno Segura, Assistant Professor
- Héctor González Pons, PhD student
- Mónica Martínez Jordà, PhD student

o) Contact details of the principal investigator for questions or clarifications:

For any clarification or inquiries, you may contact the principal investigator:

Pilar Serra Añó

Email: pilar.serra@uv.es

Telephone: 655069670

p) Ethical criteria:

The project will be carried out in accordance with the international ethical criteria set forth in the Declaration of Helsinki.

2.- CONFIDENTIALITY AGREEMENT

a) Measures to ensure respect for privacy and confidentiality of personal data:

Appropriate measures have been adopted to guarantee the complete confidentiality of the personal data of research participants involved in this study, in accordance with the Spanish Personal Data Protection Law (LOPD) 3/2018, of December 5. (If deemed appropriate, these measures may be described in greater detail.)

b) Measures to access relevant information arising from the research or overall results:

Please note that you have the right to access the information generated about you during the study. (Briefly detail the measures taken to facilitate access to such information.)

c) Measures taken due to the pseudonymized nature of the study:

An effective pseudonymization system has been established that only allows the subsequent identification of study participants by the principal investigator and only if absolutely necessary. Any use of the study results for teaching, research, and/or publication purposes will always ensure proper anonymization of personal data so that research participants will not be identified or identifiable.

3.- CONSENT

In the event that the research participant is of legal age:

Mr./Ms._____,
of legal age, holder of National ID number: _____, hereby states that:

I have been informed about the characteristics of the Research Project entitled:
"EFFECTIVENESS OF PAIN NEUROSCIENCE EDUCATION COMBINED WITH THERAPEUTIC EXERCISE IN PEOPLE WITH CHRONIC PAIN."

I have read both Section 1 of this document entitled "Information for the Research Participant" and Section 2 entitled "Confidentiality Agreement," and I have been able to ask any questions that arose in relation to them. I believe that I have understood the information provided.

I have been informed of the possibility of withdrawing from the study at any time.

Under these conditions, I consent to participate in this study.

In witness whereof, I sign this document at the place and date indicated below.

Valencia, _____ of _____***, 20***.

First and last name of the participant: Signature:	First and last name of the father, mother, or guardian (in the case of minors or legally incapacitated persons): Signature:	First and last name of the principal investigator: Signature:

If the study participant is an adolescent between the ages of 12 and 16 who is intellectually and emotionally capable, their opinion must be heard, and they must authorize their participation in the study by also signing this consent form. In the case of minors who are neither legally incompetent nor incapacitated, but who are emancipated or have reached the age of 16, consent cannot be given by a representative, and the study subject must sign the consent form personally (Law 41/2002).

WITHDRAWAL OF CONSENT

I hereby withdraw the consent I provided on _____ to participate in the project titled "EFFECTIVENESS OF PAIN NEUROSCIENCE EDUCATION COMBINED WITH THERAPEUTIC EXERCISE IN PEOPLE WITH CHRONIC PAIN," and, for the record, I sign this withdrawal.

In Valencia, on the _____ of _____***, 20***.

First and last name of the participant: Signature:	First and last name of the father, mother, or guardian (in the case of minors or legally incapacitated persons): Signature:	First and last name of the principal investigator: Signature: