Efficacy of Two Physiotherapy Intervention Methods Applied in Subjects in the Social-healthcare Setting With Nonspecific Neck Pain.

ID: 38/2014

INFORMED CONSENT

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Mª de los Ángeles Cardero Durán
mcarderod@unex.es

INFORMED CONSENT

Project: EFFICACY OF TWO PHYSIOTHERAPY INTERVENTION METHODS APPLIED TO SUBJECTS IN THE SOCIAL-HEALTH FIELD WITH NON-SPECIFIC NECK PAIN.

Patient: _____ **Patient ID#:** _____

Centre: _____ **Centre ID#:** _____

Researcher(s): _____

The responsible researcher, Mª Ángeles Cardero, can be contacted at any time, in order to obtain information about the project, by telephone 635501301, email mcarderod@unex.es, and at the following address: Departamento de Terapéutica Médico-Quirúrgica, Facultad de Medicina y Ciencias de la Salud, Badajoz.

PLEASE, READ THE INFORMATION CONTAINED IN THIS DOCUMENT CAREFULLY AND MAKE SURE YOU UNDERSTAND THIS RESEARCH PROJECT. PLEASE SIGN THIS DOCUMENT IF YOU AGREE TO PARTICIPATE IN THIS STUDY. BY YOUR SIGNATURE YOU ACKNOWLEDGE THAT YOU HAVE BEEN INFORMED OF THE CHARACTERISTICS OF THE PROJECT, ITS REQUIREMENTS, AND ITS RISKS AND THAT YOU FREELY AGREE TO PARTICIPATE IN IT. A COPY OF THIS DOCUMENT WILL BE GIVEN TO YOU.

OBJECT OF THE STUDY.

You have been invited to participate in a research study aimed at THE IMPROVEMENT OF UNSPECIFIC CERVICAL PAIN..

PROCEDURES AND DURATION OF THE STUDY.

The only procedure to which you will be subjected will be:

- Initial assessment with application of the different questionnaires.
- Intervention through 10 physiotherapy sessions aimed at reducing non-specific cervical pain. Two types of interventions according to experimental group based on massage + TENS type currents and massage + stretching.
- Final assessment with application of the different questionnaire.
- The control group will only undergo the examination tests and questionnaires.

The duration of the project will be 5 weeks, during which you authorise us to evaluate you and to carry out the individual physiotherapy sessions. The data you provide will be used exclusively for non-profit research purposes.

RESULTS OF THE STUDY

At the end of the study, you will be informed of the overall result of the study if you wish, but NOT of your personal result, which will be treated with complete confidentiality in accordance with the Declaration of Helsinki and the Biomedical Research Act 14/2007.

RISKS ARISING FROM PARTICIPATION IN THE STUDY.
The risks associated with participation are: THERE ARE NO ASSOCIATED RISKS.

BENEFITS.

Participation in the project will not be financially rewarded. Apart from the above, it is estimated that the development of the study in which you will participate will bring benefits in the improvement of INESPECIFIC CERVICAL PAIN.

COSTS.
El coste del procesamiento de los datos, así como los análisis posteriores serán cubiertos por el proyecto. Su participación no le supondrá ningún coste.

CONFIDENTIALITY OF YOUR DATA.

In accordance with current legal regulations, the results of the information obtained will be treated with total confidentiality. The data collection protocol will be archived, and each participant will be assigned a password so that the information obtained cannot be linked to the subject's identity. The data will be anonymised, ensuring the impossibility of inferring their identity, for their study and potential subsequent analysis.
The responsible researcher undertakes that the confidentiality of the data that may be obtained in this project will be scrupulously observed, and that the personal data of the participating subjects will be known only to the principal investigator and collaborators of the project. In appropriate cases, the principal investigator will inform the medical officer or those concerned if it is believed that any result of the project could be of interest to them.
The responsible researcher undertakes not to use the data for studies other than those of this project and not to transfer the data to other possible projects or research teams.
For all matters not foreseen in this document, the current legislation on personal data protection will be applied (Law 41/2002, of 14 November, basic law regulating patient autonomy and rights and obligations regarding clinical information and documentation, BOE 274 of 15 November 2002; Ley Organic 3/2018 de 5 de December de 5 de December de Protection de Dates Personal's y guarantee de rights digitals, BOE 294 de 6 de December de 2018), on biomedical research (Ley 14/2007, de 3 de Julio, de 3 de Julio, de Investigation biomedical; BOE 159 de 4 de Julio de 2007) and any other applicable law.
The results of the study may be published in scientific journals or general publications.
However, the information concerning your participation will be kept confidential.
You will receive a copy of this Informed Consent signed by you.

PATIENT DECLARATION.

I have been informed by the staff involved in the above-mentioned project:

● Of the advantages and disadvantages of this procedure.

● Of the purpose for which my data will be used.

● That my data will be used exclusively for non-profit research purposes.

That my data will be provided anonymously to the researchers of the project.

That I can at any time request generic information about the studies for which my data have been used.
I have understood the information I have received and have been able to ask any questions I felt appropriate.

You have the right to participate or not in the research and to withdraw your consent at any time.

A COPY OF THIS DOCUMENT HAS BEEN PROVIDED TO ME. I AGREE TO PARTICIPATE IN THIS STUDY.

Name: .....Signature:

Statement by the researcher that he/she has duly informed the participant.

Name: .....Signature:

Date: