INFORMED CONSENT AND PATIENT INFORMATION DOCUMENT

Effectiveness of coping strategies on the control of musculoskeletal chronic non-cancer pain and quality of life: a randomized clinical trial.

This study was approved by the Ethics Committtee of the Virgen Macarena-Virgen del Rocío University Hospitals in Seville approved on July 22, 2020 with code: 1589-N-19.
(Last modified on December 15, 2020 when adding this coverpage).

Copy for patient

PATIENT INFORMATION DOCUMENT

Study data

Title: Effectiveness of Coping Strategies on the Control of Musculoskeletal Chronic Non-Cancer Pain and Quality of Life: A Randomized Clinical Trial.
Principal Investigator: Carmen Sánchez Gutiérrez, specialist in Anesthesiology and Pain Therapeutics.
Center: Hospital San Juan de Dios del Aljarafe. Bormujos (Seville)

About us

We are professionals of the Chronic Non-Cancer Pain (CNCP) Unit of the San Juan de Dios del Aljarafe Hospital and we welcome you. We want to inform you about a research project that we invite you to participate in and which we explain below.

What are we studying?

CNCP is a disease by itself, lasting more than three months and affecting not only physical factors but also emotional ones. We want to demonstrate the effectiveness of coping strategies on the control of CNCP.

How are we going to do it?

We will carry out different training activities and telephone follow-up from our hospital in order to improve pain management and quality of life. Two groups will be created assigning patients randomly.
All the patients who have decided to participate in the study will undergo telephone interviews (at the beginning, one month, three and six months) to learn about certain characteristics of their process and evaluate their evolution. You will be asked about your clinical situation, physical measurements (weight, height and abdominal circumference), drug treatment, how you are living your situation and the need to go to the emergency room or change treatment for pain. It will not take more than 20 minutes.
Any patient will have the possibility, if they wish, to receive all the activities once the study is finished. Patients over 18 years of age with CNCP from the Aljarafe Health Area may participate, up to a number of 144 participants.
If you decide to participate, you must give your consent in writing in a document called informed consent.

Does it present any kind of danger or disadvantage?

This study does not present additional risks or dangers, as it is not about evaluating a new drug or device. All patients in the study maintain or modify pharmacotherapy according to their clinical situation and according to the indications of their referring physician (Primary Care Physician or Care Specialist), without this being a different treatment for the patients who are inside or outside the studio.

What benefits will it bring me?

We can have an improvement in your pain management, however, it might not bring you any benefit. In any case, the information obtained in the study may help other patients with their disease in the future

Will I have any kind of compensation?

You should know that you will not get any financial benefit from participating in this study.

How will my data be used?

In accordance with current regulations on data protection and the provisions of Organic Law 3/2018, of December 5, on the Protection of Personal Data and guarantee of digital rights, you expressly consent to the inclusion of data from your medical history, as well as those resulting from their participation in the study in a personal data file under the responsibility of the center. Access to your personal information will be restricted to the study doctor and her collaborators, who will be subject to the duty of secrecy inherent to their profession.

By signing this document, you authorize part of your medical history to be transferred by the health center research team to the referral hospital, where the study will be completed and all documentation will be kept.

If at any time the use made of your data does not correspond to the one described above, you may exercise your rights as affected, in the terms provided by the regulations, as well as file a claim with the Control Authority (Spanish Protection Agency of data). In this sense, you can go to: Avenida. San Juan de Dios, s / n, CP 41930 Bormujos, Sevilla or contact our Data Protection Delegate through the email C15_DPO@sjd.es.

Can I leave the study once it has started?

Once your participation has started voluntarily, you can abandon it at any time, even if you have previously signed the informed consent, without having any consequence on your follow-up and/or prior medical treatment. If this circumstance occurs, we would like to know the reasons to avoid them in the future and improve the care provided, being this response voluntary.

We appreciate your time and any response. We are at your disposal.

The research team.

Copy for the Center

INFORMED CONSENT FOR PARTICIPATION IN THE STUDY "EFFECTIVENESS OF COATING STRATEGIES ON THE CONTROL OF CHRONIC NON-ONCOLOGICAL PAIN: A RANDOMIZED CLINICAL TRIAL"

I, _____

(Name and surname)

with DNI_____

- I have read the information sheet that has been given to me.
- I have been able to ask questions about the study.
- I have received enough information about the study.

I have spoken with: _____

(Name of investigator)

I understand that my participation is voluntary and that I can withdraw from the study:

- When I want.
- Without having to give explanations.
- Without this affecting my medical care.

For all the above, I freely give my consent to participate in the study and I promise not to disseminate the identity of the rest of the attendees or the content that is discussed in the workshops.

Participant Signature

Date:

Investigator Signature

Date:

In accordance with current regulations on data protection and the provisions of Organic Law 3/2018, of December 5, on the Protection of Personal Data and guarantee of digital rights, you consent to the signing of this document to the inclusion of the data from your medical history, as well as those resulting from your participation in the study in a personal data file under the responsibility of the center.

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INFORMATION FOR THE PATIENT ASSIGNED TO THE PSYCHOEDUCATIONAL WORKSHOP

Study data

Title: "Effectiveness of Coping Strategies on the control of Non-Cancer Chronic Pain: randomized clinical trial".

Principal Investigator: Carmen Sánchez Gutiérrez, specialist in Anesthesiology and Pain Therapeutics.

Center: Hospital San Juan de Dios del Aljarafe.

¿ What will my participation consist of?

We thank you for your participation in this study. All patients who have agreed to participate, like you, have been randomly assigned to a group . We inform you that, after this assignment, you will be part of the **"intervention group"** . You will continue with the pharmacological treatment indicated by your Primary Care Physician or Specialist and you will be interviewed by telephone at the beginning, one month, three and six months to evaluate your evolution. Additionally, you will receive a four-week face-to-face **psychoeducational workshop**. For this reason, we ask you to carefully read the information regarding this activity, the recommendations and regulations. We are at your disposal to answer any questions in this regard.

What is the study's psychoeducational workshop?

The psychoeducational workshop consists of a " Group modality multicomponent neuropsychological intervention program " aimed at people with a diagnosis of chronic pain not associated with cancer. It consists of 4 sessions of weekly frequency and interactive nature , with a psychoeducational structure and training in emotional self-regulation. The duration of each session will be three hours.

<u>Rules of participation and details of the workshop</u>

- The collaboration of patients is essential, ensuring attendance at all sessions from the start to the end time. The workshops will take place in the afternoon.
- Please, be punctual. Remember that each delay will affect the whole group.
- The patient does not have to provide personal or private information.
- It is mandatory to respect the confidentiality of both, the identity of the participants and the content discussed.
- It is mandatory not to publicize your participation in the workshop, so as not to influence other patients who may belong to the control group or be participants in future editions of the workshop.
- It is not a self-help group, but a workshop for learning mind-body techniques aimed at pain control.
- In each workshop, a series of tasks will be indicated that you must carry out throughout the week, until the next session, in order to apply the knowledge and tools presented in the different sessions. These tasks are mandatory for the workshop to be effective.

Copy for patient

Necessary material if you participate in the workshop

- Wear comfortable clothes.
- If due to your illness you cannot remain seated, it is necessary that you bring the material with which you are comfortable at home (cushions, pillow, mat ...).
- Bring a notebook and a pen to make notes.
- Have a cell phone to : warn of possible changes in schedules or day sessions, to be able to send audio with meditation sessions or other information and also for that will make a picture (self portrait) at the beginning and the end of the workshop (this photo will not be disseminated , it will only be saved on your mobile phone so that you can use them as you deem appropriate) .
- The rest of the necessary material will be provided by the research team.

What is the objective of the investigation?

The main objective of this work is to demonstrate that learning coping techniques and self-control when faced with pain can improve the clinical situation and the patient's quality of life.

What benefits and risks will I have with my participation in the study?

We believe that this workshop can lead to improved pain management, however it may not be of any benefit to you. In any case, the information obtained in the study may help other patients with their disease in the future.

The interventions involved in this research are safe and non-invasive or minimally invasive:

• **Telephone surveys**: patients will answer it from their home and if they cannot attend us at first, we will make an appointment to call you at the most appropriate time for the patient.

• **Psychoeducational intervention workshops** and the practice of relaxation and Mindfulness do not usually present any danger for patients. Exceptionally, paradoxical reactions have been described in patients with previous psychiatric illnesses.

• During the workshop, on a voluntary basis and to check progress in self-control, low-intensity stimuli will be used on the skin, and only to patients who request it.

We thank you in advance for your time and your response.

The research team .

In accordance with current regulations on data protection and the provisions of Organic Law 3/2018, of December 5, on the Protection of Personal Data and guarantee of digital rights, you expressly consent to the inclusion of data from their medical history, as well as those resulting from their participation in the study in a personal data file under the responsibility of the center.