FEDERAL UNIVERSITY OF SÃO CARLOS – UFSCAR

BIOLOGICAL AND HEALTH SCIENCES CENTER

DEPARTMENT OF PHYSIOTHERAPY

EFFECTS OF A FUNCTIONALITY-FOCUSED BIOPSYCHOSOCIAL MODEL IN THE CARE OF INDIVIDUALS WITH CHRONIC MUSCULOSKELETAL PAIN IN A SPECIALIZED HEALTH SERVICE – A RETROSPECTIVE COHORT STUDY

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SÃO CARLOS
2026

Informed Consent Form (ICF)

FEDERAL UNIVERSITY OF SÃO CARLOS
INFORMED CONSENT FORM
(Resolution No. 510/2016 of the National Health Council)

2025-04-10

You are being invited to participate in the study entitled:
"Effects of a biopsychosocial model centered on functionality in the care of individuals with chronic musculoskeletal pain in a specialized health service – a retrospective longitudinal study."

The study will be conducted at the Pain Clinic in São Carlos, at the School Health Unit (USE), located at the Federal University of São Carlos (UFSCar). Its objective is to understand whether a treatment model focused on improving functionality (i.e., daily life activities) is more effective in caring for individuals with chronic pain than a model focused on pain control. Both models will be carried out by an interdisciplinary team of professionals.

This study is justified by the need to identify better ways to assess and treat chronic pain in an integrated manner, promoting more effective clinical practice. Additionally, the study will evaluate the costs and benefits of this type of treatment by monitoring changes in pain and functionality of participants over time, which may help improve care and optimize resources.

You will be selected and included in the study if you meet the inclusion criteria and participate in one of the therapeutic approaches offered at the clinic, which may be either the pain-focused model or the functionality-focused model, depending on the date of your admission to the health service. In addition, you will receive specialized treatment for your complaints, complete questionnaires, and undergo clinical assessments at the beginning and end of the treatment, with follow-up by an interdisciplinary team over a three-month period. During this time, you will be required to attend the USE once a week, on Friday afternoons, with each session lasting approximately 60 minutes, totaling around 12 sessions.

The questionnaires you will complete will address aspects related to your pain, quality of life, functionality, and psychosocial factors, assisting in the overall evaluation of treatment effects. These questionnaires will later be accessed for statistical analysis.

Your contribution will involve the use of information from your medical records, including clinical data and records of assessments carried out during your treatment, based on the intervention model to which you were assigned.

Your participation is voluntary, and you may refuse or withdraw at any time without any penalty or prejudice to your relationship with the institution or the professionals involved. All data collected during the study will be stored confidentially and anonymously through coding, ensuring that your identity and privacy are preserved. The results of the study will be presented at scientific events and published in journals, without individual identification of participants.

The benefits of your participation include receiving interdisciplinary and specialized care, with monitoring and support during treatment for pain control and improvement of functionality, as well as contributing to the advancement of scientific knowledge in this field. This study does not present significant risks; however, there may be some discomfort when answering questionnaires about your health condition, although clear explanations will be provided regarding their necessity for the research. There may also be a risk of fatigue or tiredness due to exercises performed during treatment, but these will always be carefully supervised, with assistance provided in case of any adverse events. If necessary, you will be referred to psychological support at the School Health Unit of UFSCar, in order to provide care for as long as needed.

All data will be collected ensuring confidentiality, so that names or any other stored information will not allow participant identification. In addition to these risks, there are also risks related to the use of virtual platforms for data storage, such as privacy breaches, confidentiality violations, and exposure of clinical data that could lead to participant identification and disclosure of confidential information. To minimize these risks, confidentiality of the responses will be ensured, and they will be treated as confidential and used exclusively for scientific purposes. Participants have the right to withdraw their consent or discontinue answering questionnaires at any time if they choose to withdraw from the study. Furthermore, all necessary measures will be taken to ensure confidentiality and proper storage of collected data, with a commitment not to publish names (not even initials) or any information that could allow individual identification.

Regarding virtual data collection, there are inherent risks associated with such platforms, including potential breaches of shared information and platform privacy policies. Researchers have limitations in guaranteeing absolute confidentiality, and there is a potential risk of violation; however, this risk will be minimized since only the audio of interviews will be

recorded, and only the researchers involved will have access to these recordings. Additionally, access to meetings will be sent exclusively and directly to the participant's provided email address.

Participation in this study is free of charge, with no financial compensation. Any transportation or food expenses resulting from clinic evaluations will be reimbursed upon proof, if applicable. In the event of any harm resulting from your participation, you will be entitled to full assistance and may claim compensation for as long as necessary, according to the evaluation of a specialized committee.

This research project will be conducted following approval by the UFSCar Research Ethics Committee, which is responsible for ensuring the ethical conduct and safety of research participants. If you have any questions or concerns about your rights, you may contact the Human Research Ethics Committee (CEP) of UFSCar, which is linked to the University's Office of Research, located in the administrative building (south area of the São Carlos campus).

The CEP is linked to the National Commission for Research Ethics (CONEP) of the National Health Council (CNS), and its operation is governed by CNS/CONEP regulations. CONEP is responsible for implementing regulatory standards and guidelines for research involving human beings, approved by the CNS, and works in conjunction with a network of Research Ethics Committees (CEPs) organized within institutions where research is conducted.

I declare that I have understood the objectives, risks, and benefits of my participation in this research and agree to participate.

_____, _____ of _____ of _____

Participant's Signature

Researcher's Signature
