30 Semptember 2020

Effects of Multimodal Exercises Integrated With Cognitive-behavioral Therapy in Subjects With Chronic Neck Pain: a Randomized Controlled Study With One Year Follow-up

NCT ID not yet assigned

INFORMED CONSENT FORM

Dear Patient,

this study aims to investigate and evaluate the efficacy of a multidisciplinary program that integrates cognitive-behavioral therapy based on kinesiophobia, in the treatment of chronic neck pain.

The research project manager is Professor Marco Monticone from the Department of Medical Sciences and Public Health of the University of Cagliari, Physical and Rehabilitative Medicine. We ask for your willingness to participate in the research. Before deciding whether or not to give your consent it is important that you listen carefully to the following information regarding the objectives of the research and how it is conducted.

Please take the time to understand the following information and do not hesitate to ask for clarification or further information.

The research has the primary objective of verifying the effectiveness of a multidisciplinary program in inducing clinically significant and long-term improvements in the disability, pain and quality of life of subjects suffering from chronic neck pain. It also aims to assess the work discomfort linked to the condition of chronic neck pain.

Participation in this study is voluntary, so you can refuse to give your consent. If you decide to accept, you will be asked to verbally confirm your consent to participate in the research and your consent to the use of the data collected through your participation. The consent can be withdrawn at any time, without this having any negative consequences, and without the need to specify the reason.

If you agree to participate in this research, you will be asked to answer the questions of specific questionnaires aimed at investigating socio-demographic, clinical and occupational aspects concerning your situation.

If you accept to participate in this research, you will be included in one of the two rehabilitation paths provided for by the study protocol in question: multidisciplinary or general. Pursuant to the European Regulation on the Protection of Personal Data (GDPR 2016/679), articles 5 (Principles applicable to the processing of personal data), 6 (lawfulness of processing) and 7 (conditions for consent), the data collected will be used exclusively for scientific research purposes. All information collected will be stored securely and prevented from being viewed by outsiders. Any information that could identify the participants will be removed to ensure their anonymity. The material will be kept by the head of the study.

There are no physical risks involved in participating in this study. However, it may happen that you feel uncomfortable answering some interview questions. In this case, please remember that it is your right not to respond, and, if you deem it, to stop participating in this study and revoke the consent previously provided.

There are no direct benefits. However, also thanks to your participation it will be possible to deepen the knowledge related to rehabilitation treatments in chronic neck pain.

The results of the research, also processed by means of electronic means, will be disseminated only in strictly anonymous form, for example through scientific publications, statistics and scientific conferences. Your participation in the study implies that, in compliance with the legislation on clinical trials, the staff assigned to the study, the ethics committee and the Italian and foreign health authorities, will be able to know the data concerning you, also contained in your original clinical documentation, with ways to guarantee the confidentiality of his identity.

If you have any questions or doubts about the research in question, you can contact prof. Marco Monticone, telephone 070.6753109, email marco.monticone@unica.it

The protocol of the illustrated trial was drawn up in accordance with the standards of good clinical practice of the European Union and the current revision of the Declaration of Helsinki, and was submitted for approval by the Ethics Committee of the AOU of Cagliari.

If you decide to withdraw your consent and interrupt your participation in the research, you will not renounce any legal right acquired through participation in the research.

We thank you for your cooperation.

Signature of the patient

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Signature of the investigating physician

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