Efficacy of Kinesio Taping in Musculoskeletal Neck Pain in Short and Medium Term. A Randomized Control Double Blinded Clinical Trial

TITLE: Efficacy of Kinesio Taping in Musculoskeletal Neck Pain in Short and Medium Term. A Randomized Control Double Blinded Clinical Trial

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PROJECT ENTITIES: COMPLUTENSE UNIVERSITY OF MADRID & NURSERY, PHYSIOTHERAPY AND PODIATRY FACULTY.

NUMBER OF IDENTIFIACTION:

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Facultad de Enfermería, Fisioterapia y Podología
Universidad Complutense de Madrid

UNIVERSIDAD COMPLUTENSE MADRID

STUDY PROTOCOL

Type of Study: A double-blind controlled clinical trial was conducted with 30 days following.

Target population: Population with musculoskeletal neck pain.

Sample: A convenience sampling will be carried out among the patients according to eligibility criteria.

Inclusion criteria:

-Age between 18 and 30 years old,

-Presence of myofascial pain syndrome (MPS) and myofascial trigger point (MTP) in the upper trapezius muscle, according to the diagnostic criteria proposed by the American Academy of Pain Medicine and the scientific community a) tender point on palpation, with or without referred pain b) patient recognizes pain during tender point palpation c) at least three of the following: muscle stiffness or muscle spasm, limited range of motion in an associated joint, increase of pain with stress, palpation of tight band and / or nodule, associated with a tender point

-Understand written Spanish.

Exclusion Criteria:

-Neck pain of traumatic origin, due to recent surgery or causing radiculopathy.

-Have been diagnosed with chronic pathology, as well as neoplastic or suspicion of it.

-Have received some type of pharmacological or non-pharmacological analgesic treatment in the last 30 days

- Pregnant or menstrual women.

Sample size

The required sample size was calculated using the G * Power software (G * Power version 3.1.9.6). To identify the differences between the 3 intervention groups at the 3 evaluation moments, the sample size was estimated based on finding a moderate effect size (Cohen's f = 0.25). Considering an alpha error of 5% (0.05) and a beta error of 10% (statistical power of 0.9), he estimated the need for a sample size of at least 45 patients in total.

Procedure

During the months of May to July 2021, a research assistant will contact potential participants who will be invited to participate in this study. Once they agree to participate, it will schedule for a face-to-face consultation at the university, where the main researcher will inform the study participants. Once the information sheet and informed consent will be a sign, an investigator will carry out the

measurements of the variables for initial data collection in the first session. In another room, an expertise physiotherapist with experience in applying Kinesio taping will perform interventions on patients on the same day as the initial evaluation. It this way, the investigator that will assess outcomes will be blind to the treatment that each patient will receive.

At the second consultation, 4 days after the first, the same physiotherapist who applied the bandage will remove it from the patients who will receive it and any remains of the bandage on the skin were cleaned. For patients in the control group (nothing apply), it will be the same protocol to alter not the double-blind. The principal investigator will perform the evaluations and data collection without knowing the intervention the patient will receive. In a third consultation, as a follow-up (30 days after the second consultation), the collection of the same measurements and clinical variables from the patients who completed the process will repeat by the same investigator that did the outcomes' assessment.

The information sheet, the informed consent, and the evaluation instruments will be collected by a researcher, stored, and guarded in the Department of Radiology, Rehabilitation and Physiotherapy of the Complutense University of Madrid. Thus, complying with the provisions of Organic Law 3/2018, of December 5, on the Protection of Personal Data and guarantee of digital rights.

Ethical Aspects

The study has the approval of the research commission of the Faculty of Nursing, Physiotherapy and Podiatry of the Complutense University of Madrid. Also, with the favorable opinion of the research commission of the Hospital Clinico San Carlos, Madrid. Lastly, it will be evaluated by the Ethics Committee of the research institute Hospital Clinico San Carlo Madrid, Instituto de investigación Sanitaria Hospital Clínico San Carlos (IdISSC).

The study will comply with all the ethical principles of the Declaration of Helsinki. All participants will participate in the study on a voluntary basis. They will be informed of the objective of the study, the procedure, and the process of carrying it out. In addition, the informed consent of each participant and their guardians will be required, which may be revoked at any time. In addition, they are within their right to know the results of the investigation once it has been completed.

The clinical and personal information will be totally confidential where the researchers will comply with the confidentiality commitments of the hospital center and the Faculty of Nursing, Physiotherapy and Podiatry. The treatment, communication and transfer of personal data of all participating subjects will comply with the provisions of the General Regulations for the Protection of Personal Data (Regulation 2016/679 of the European Parliament) and Organic Law 3 / 2018, of December 5, Protection of Personal Data and guarantee of digital rights.

Therefore, it is considered that carrying out the study complies with the ethical and research standards and that the benefits in knowledge in the field that can

be derived from it could significantly improve the healthcare activity, not assuming the realization of this, a serious damage to patients, families or professionals.