Universidad Rey Juan Carlos

PERCUTANEOUS ELECTRICAL NERVE STIMULATION OF THE MANDIBULAR NERVE FOR THE MANAGEMENT OF PAIN AND FUNCTIONALITY IN PATIENTS WITH TEMPOROMANDIBULAR DISORDERS.

Controlled and Randomized Trial.

Study Protocol

The sample subjects will include patients attending the Origenkinesis physiotherapy center in Alcorcón (Madrid). Patients under the age of 18 will not be admitted to the study. Patients will also be assessed using the research diagnostic criteria for temporomandibular disorders (RDC/TMD) introduced by Dworkin and LeResche in 1992. This allows standardization of procedures for epidemiological studies, the unification of diagnostic and exploratory criteria for TMD, and comparison of results with other similar studies. All researchers will be trained and calibrated according to the adopted standards presented on the official website of the International RDC/TMD Consortium. Participants will be randomly allocated to two groups: 1) an experimental group receiving an intervention based on PENS (Percutaneous Electrical Nerve Stimulation), manual therapy, and exercises; 2) a control group receiving only manual therapy and exercises. Randomization will be concealed and carried out using the GraphPad program. All patients will be informed about the study participation terms and will give their informed written consent during enrollment. The study will take place at the Origenkinesis physiotherapy and exercise center located at 7 Las Gardenias Street, Alcorcón (Madrid). The evaluator will be a physiotherapist specializing in musculoskeletal and neural pain, experienced in managing patients with TMD, who will analyze participants without knowing their assignment to the experimental or control group. Based on observations during the evaluation process, the physiotherapist will explain to the patient the findings from the examination, the suspected condition, and propose the treatment plan. In the first session, each patient will undergo a medical history review and a comprehensive examination to rule out any possible contraindication suggesting an underlying medical condition. Before the specific evaluation of temporomandibular dysfunction and pain, a physical examination of the cervical spine will be performed. The cervical spine examination will include an active range of motion test for flexion, extension, bilateral lateral flexion, and rotation without/with overpressure. In the temporomandibular examination, the range of mouth opening will initially be measured using

a calibrated Therabite® System device. Then, pain will be assessed using the NPRS scale at rest and with maximum possible bite force. Subsequently, a manual trigger point screening will be conducted on the masseter muscle, followed by algometric measurement at tender points of the masseter. Before and after treatment, we will measure masseter activation using surface electromyography during maximum occlusion and chewing gum. Before commencing treatment, the patient will complete a disability-related TMD questionnaire, a self-assessed quality of life questionnaire, and the Helkimo and Krogh-Paulsen questionnaires. At the fourth final assessment, they will fill these out again alongside a GROC (Global Rating of Change) satisfaction scale regarding the treatment.

Statistical Analysis Plan

A controlled and randomized study with single blinding. Sample size estimation will be conducted using the GPower 3.1 program with the following parameters: effect size of 0.4, alpha error of 0.05, power of 0.80, two groups, and four measurements. Considering these parameters and a potential 10% loss rate, a sample size of 50 subjects is estimated. In the statistical analysis, variable contrasts will be conducted using the SPSS v27 program through repeated measures ANOVA if the variables follow a normal distribution. Otherwise, the Friedman test will be used. Normality will be checked using Shapiro-Wilk and Kolmogorov tests.

DATE: 25/7/2023