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Randomized clinical trial of electrostimulation therapies with an electromyographic multifractal analysis device for patients with temporomandibular disorders

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Introduction

Temporomandibular dysfunction or disorder (TMD) is a functional disorder of the temporomandibular joint (TMJ), and is the cause of non-dental pain in the orofacial region.

TMD presents diagnostic difficulties, the literature suggests objective assessment of neuromuscular activity. Electromyography (EMG) is a reliable tool to determine the degree of functional muscle alteration, the EMG signal can be estimated and characterized by multifractal analysis, for example, the Hurts Index. This method is used successfully in the study of physiological signals with high biological variability (signals: cardiac, cardiovascular, ophthalmological, neuronal, metabolic, etc.), it is considered suitable for the comprehensive analysis of neuromuscular behavior. (1-3) (1)

The main objective of TMD treatment is to restore chewing function with splints being the first choice; however, complementary therapies are recommended for the relief of signs and symptoms. Electrostimulation has been reported to produce favorable analgesic effects in the treatment of TMD. Electrostimulation can be applied in two ways; transcutaneous and percutaneous, both produce muscle contraction by activating the nervous system. However, the degree of activation determines the magnitude of the effect on organic functions. The clinical results obtained depend on the selected point to be stimulated, as well as the stimulus method used and the duration of the stimulus. The transcutaneous route known as Transcutaneous Electrical Nerve Stimulation (TENS) produces indirect contraction of the muscle belly in a superficial way with the use of electrodes and the percutaneous route called Percutaneous Neuromodulation Therapy (NPT) produces direct stimulation of the muscle fibers through the insertion of needles. (electroacupuncture).

The objective of this study is to compare the neuromuscular effect produced by transcutaneous and percutaneous electrostimulation therapies as adjuvants in the treatment of TMD through the use of an occlusal splint in patients from the Physiology Laboratory of the Division of Graduate Studies and Research (DEPeI) UNAM.

Theoretical framework

The American Association defines temporomandibular dysfunction (TMD) as a group of functional alterations of the masticatory system. (4) Worldwide they are the second most frequent skeletal muscle condition and between 7 and 15% of the adult population is affected, it is a functional disorder of the temporomandibular joint (TMJ). (5-6) (5) (6)

It is identified by the presence of muscle or joint pain, joint noises, and restriction, deviation, or deflection in the mandibular opening. (7) It is the main cause of non-dental pain in the orofacial region (8), it is estimated that 75% of the population has had some sign throughout their life and 33% some symptom of these; 30% are diagnosed and only 5 to 10% request treatment (9). It occurs between

20 and 40 years of age with greater frequency in women (ratio of 3: 1 to 6: 1) (10). The etiology of TMD is diverse and is associated with parafunctional habits, psychosocial disorders, inflammatory disorders, infectious problems, trauma, and hormonal changes. (10)

TMD presents diagnostic difficulties complicating treatment planning (6-7). The literature suggests objective assessment of masticatory function and frequent monitoring of neuromuscular activity through electromyography studies. (eleven)

Electromyography (EMG) is a reliable tool to determine the degree of muscle functional alteration (12); it is an auxiliary for the diagnosis and treatment of TMD. The electromyographic analysis tools offered by modern digital systems are: RMS (root mean square), DFA (detrended fluctuation analysis) MAV (mean absolute value), ARV (average rectified value) and MNF (mean frequency). Most EMG signals are based on the analysis of their stochastic characteristics in time and frequency. (13) The EMG signal exhibits a chaotic behavior which can be estimated by its fractal dimension using non-linear techniques, for example, the Hurst index. This method has been used successfully in the study of physiological signals with high biological variability and is considered suitable for the comprehensive analysis of neuromuscular behavior. (14)

The main goal of treating TMD is to restore function; the clinical challenges are; reduce or eliminate joint pain and / or noise and regain normal jaw movement. Currently there are different types of treatments such as the use of occlusal splints, pharmacological treatments, infiltrations, arthroscopy, arthrocentesis or surgery. Splints are the first-line treatment with a conservative and valuable approach in the remission of signs whose objective is to generate functional stability (15), frequently it is complemented with the use of drugs for the remission of symptoms (16). The American Academy of Orofacial Pain recommends analgesic focus therapies with the use of an occlusal splint, for example: muscle stretching and exercises, trigger point injections, electrotherapy (electrostimulation), dry needling (acupuncture), or massage therapy. These alternatives reduce pain, restore function, and some reduce stress and anxiety. (17)

Myofascial pain is myogenic in origin and it has been reported to decrease significantly with electrical stimulation, which has analgesic and anti-inflammatory effects on the muscles (18); the physiological mechanism by which electrical currents act is known as "gate theory." When electrical stimuli are administered, Aβ fibers are activated, modulating the nervous system and interrupting the transmission of nociceptive information. The results obtained with electrical stimulation depend on the selected point to be stimulated, the stimulus method used and the duration of the stimulus. (19)

Different therapies based on the same principle are applied in dentistry and it has been observed that the degree of activation determines the magnitude of the effect on organic functions, for example, the inhibition of pain. (20) Studies differ on the location of the area to be stimulated, the length of time the stimulus should last, and the amount and frequency of therapies. (21) For the treatment of TMD, electrostimulation can be applied through two main routes; transcutaneous and percutaneous; both produce muscle contraction by activating the nervous system. The transcutaneous route known as Transcutaneous Electrical Nerve Stimulation (TENS) produces indirect contraction of the muscle belly in a superficial way with the use of electrodes. The

percutaneous route, also called Percutaneous Neuromodulation Therapy (NPT), produces direct stimulation of muscle fibers through the insertion of needles (electroacupuncture). (22)

Transcutaneous Electrical Nerve Stimulation, also called transcutaneous electrostimulation, consists of the application of electrical current to the skin with surface electrodes. Which is endorsed by the Food and Drug Administration (FDA) (23) as an effective method for the treatment of pain (24) the FDA recommends its use under the direction of a health professional (25) The mechanism of action of transcutaneous electrostimulation consists of activating nerve endings in the skin (26) producing changes at the cerebral and cortical level, altering the neural axis. (27)

Percutaneous Neuromodulation Therapy or percutaneous electrostimulation also called electroacupuncture, acts by administering direct electrical current to deep muscle tissues and stimulates thick afferent fibers (sensory fibers) located at the origin of pain.

(28) (29) The World Health Organization (WHO) concluded that chronic facial pain including craniomandibular disorders respond well to acupuncture treatment (electroacupuncture). Electrostimulation is approved for the treatment of chronic pain by the National Institutes of Health in the United States, Germany, and the United Kingdom. (27-31) The mechanism of action results from a multifactorial process triggered after stimulation of demyelinated nerve fibers, activating three main regulatory centers (the spinal cord, the midbrain, and the hypothalamic-pituitary axis) responsible for neuromodulation. Regulates sensory, motor and autonomic functions and involves the interaction of neurotransmitters of the nervous system (endogenous opioids with the substance

P, acetylcholine, serotonin, norepinephrine, and gamma-aminobutyric acid (GABA)). Electroacupuncture is considered less invasive than transcutaneous electrical stimulation due to its ability to act on the central nervous system. (30)

Background

The literature refers that the treatment of temporomandibular disorders is complex due to the variability of signs and symptoms in each patient. The current approach involves the implementation of techniques typical of complementary medicine for the relief of the main signs (joint noise and mandibular dysfunction) and recurrent symptoms (myofascial and / or joint pain) of this pathology. (7)

They have suggested various treatment modalities in the management of TMD. These recommended therapies include different types of interocclusal appliances, occlusal adjustment, physical therapy, jaw exercises, acupuncture, transcutaneous electrical stimulation, cognitive-behavioral therapies and pharmacological interventions (31-32) (31) (32)

The results of the efficacy of splints have shown that the success of the treatment is not clearly explained as a specific therapy, however it is the most commonly applied treatment modality in dentistry for TMD (33) In the United States a survey showed that the Most dentists treating patients with TMD preferred to wear hard splints. (34) This modality is the primary approach and is generally used as adjunctive therapy to control the associated symptoms of TMD. (35)

Although not conclusive, the results of the studies support the decompressive effect produced by the use of a splint, suggesting that it uniformly elevates the occlusal plane, displaces the bite force vector distally and decreases the length of the resistance arm in relation to the arm of the splint. effort by reducing the force directed at the TMJ. (36)

Only a few studies focused on occlusal splint therapy have been reported and therapeutic success is affected by the dentist's lack of knowledge of TMD, the duration of therapy, the type of splint and the occlusal adjustment. (37)

A systematic review article published in 2007 (Macedo CR, Silva 2007) affirms that the splint is effective to treat TMD or bruxism, however it questions that its use may be limited in the complete remission of symptoms, justifying the use of physical therapies as adjuvants in the treatment of TMD. (38) The use of physical therapies such as electrostimulation are therapeutic aids that produce analgesic and muscle relaxation effects.

Controlled studies have been reported with the application of transcutaneous electrostimulation therapies in patients with severe symptoms of TMD, which reported a significant decrease in myofascial pain, muscle and joint sensitivity measured by visual analog scale (VAS) after four transcutaneous electrostimulation therapies. . (28 and 30)

However, other authors conducted clinical trials to evaluate mandibular function evaluating signs of TMD. They reported an increase in mouth opening of 4 to 6 mm ($p = 0.002$) after transcutaneous electrostimulation therapies and observed a decreasing trend in the TENS study group after a few weeks. (36-37)

Percutaneous electrostimulation is a modality frequently used in Traditional Chinese Medicine (TCM) widely used in the treatment of various health ailments, it is one of the most studied and documented therapeutic modalities in the field of medicine, the mechanism of action has resulted controversial despite the fact that positive effects are observed from the moment in which the puncture is performed. The results depend on the selected point to be stimulated, the stimulus method used and the duration of the stimulus. (39)

At present this practice has spread and various types of therapies have been generated. (20) Auriculotherapy, Electro Acupuncture (EA) and trigger point injections (Ashí Point), are some types of acupuncture therapies that exert analgesic action for the treatment of TMD. However, EA offers advantages over manual acupuncture because parameters such as intensity, frequency, and duration of the stimulation pulse can be reliably standardized. (18) (40)

Some studies carried out in patients with TMD evaluated the analgesic efficacy of electro acupuncture compared with a control group (use of a splint) which showed a significant decrease in the levels of muscle and joint pain, with an increase in jaw function compared to the control group. (25 and 39)

The low frequency and high intensity stimuli generated by these therapies release β-endorphins and decrease pain favorably, studies have been reported comparing the frequency and intensity in TMD therapies by modifying the time of electrical stimulation in each group, reported that the 85% of the

patients in the group with continuous electrostimulation (20 minutes) presented symptoms of immediate relief at the end of therapy. (41)

The table shows the results obtained from the treatments for TMD using transcutaneous and percutaneous electrostimulation and the use of a splint:

Transcutaneous electrical stimulation for the treatment of TMD						
	N	**Sample Features**	**Interventions**	**Therapeutic application**	**Variables**	**Results**
Seifi (2017)	40	18-50 years Headache and / or neck pain. Sensitivity to palpation in the auricular area. Mouth opening limitation	Group. study: TENS therapy (n = 20) Control group: Therapeutic Laser (n = 20).	30 minutes 4 session per week 4 sessions	• Maximum mouth opening (mm) • Head and Neck Pain (EVA) • Muscle sensitivity (EVA) • Joint sensitivity (EVA)	• Maximum mouth opening: NS differences between groups • Analog visual scale (VAS): Decrease (p = 0.000) in the TENS group • Muscle sensitivity: Decrease (p = 0.000) in the TENS group • Joint sensitivity: Decrease (p = 0.000) in the TENS group
Ferreira (2017)	40	20-65 years Chronic pain (RDC / TMD)	• Group. study: TENS Therapy (n = 20) • Group. study: TENS Placebo (n = 20)	50 minutes 1 session per week 1 sessions	• Muscle pain (EVA) • Palpation muscle pain sensitivity (EVA)	• VAS: Decrease (p> 0.05) in group of placebo TENS • Palpation muscle pain sensitivity: Increase in masseter and temporal muscles in the TENS group (p> 0.05)

Percutaneous electrical stimulation for the treatment of TMD						
	N	**Sample Features**	**Interventions**	**Therapeutic application**	**Variables**	**Results**
Vera Zotelli (2017)	40	20 a 60 años Disfunción temporomandibular (Dolor orofacial y/o Limitación a la apertura bucal)	• Group. study: Acupuncture (n = 20) • Control group: Acupuncture placebo (n = 20)	55-65 minutes 1 session per week 4 sessions	• Orofacial pain (EVA) • Mouth opening (mm) • Energy in the meridians by (Ryodoraku)	• The placebo group had no decrease in pain (p = 0.2261), nor an increase in mouth opening comparison (p = 0-05) • Post-acupuncture energy level decreased in Yang channels in all sessions
Jiang-hong (20019)	40	20 to 60 years Myogenic temporomandibular dysfunction	• Group. study: Acupuncture (n = 20). • Control group: Occlusal splint (n = 20)	20 minutes 1 session per week 4 months	• Electromyographic muscle effect • Pain intensity: EVA (Beginning and end of treatment))	• VAS: decreased equally in the two groups (p = 0.001) • Right temporal muscle intensity decreased in the final stage of the splint group (p = 0.005) • Both groups decreased pain intensity short term (2 weeks)

Definition of the problem

Treatment of TMD is complex due to the variability of signs and symptoms; The use of an occlusal splint is the treatment of first choice for the stomatologist, however, this alone does not have the capacity to eradicate all the symptoms. The literature suggests the use of complementary therapies to restore chewing function.

Electrostimulation therapies produce favorable effects in the treatment of TMD. Electrostimulation can be applied in two ways: transcutaneous and percutaneous; however, the clinical results obtained depend on the technique used.

The neuromuscular effect of transcutaneous and percutaneous electrostimulation therapies has not been reported as adjuvants in the treatment of TMD through the use of an occlusal splint; The electromyographic evaluation with the multifractal analysis tool will determine the neuromuscular effect produced by the therapies, objectively evaluating the effectiveness of each one.

Research question

What is the neuromuscular effect produced by transcutaneous and percutaneous electrostimulation therapies as adjuvants in the treatment of TMD compared to the use of an occlusal splint in patients of the Laboratory of Physiology of the Division of Graduate Studies and Research DEPeI, UNAM?

Justification

TMD is the main cause of non-dental pain in the orofacial region. It is important to optimize conventional treatment (use of an occlusal splint) for the complete remission of the symptoms; As well as evaluating the neuromuscular effect produced by electrostimulation therapies as an adjunct in the treatment of TMD.

The literature suggests the objective assessment of chewing function by electromyography for the diagnosis and during treatment of TMD.

General purpose

To compare the neuromuscular electrical activity (RMS) and muscle fatigue (Hurst index) of the masseter muscles in three groups of patients with different treatments for TMD (GA = Transcutaneous electrostimulation and splint, GB = Percutaneous electrostimulation and splint, and GC = Occlusal splint.) through 6 electromyographic records scheduled weekly in patients from the Physiology Laboratory of the Division of Graduate Studies and Research (DEPeI) UNAM, admitted during the period from August to December 2020.

Specific objectives

o Register the sociodemographic and clinical variables (age, sex, TMD, BMI, systemic diseases, use of prostheses, number of teeth present, drug intake) prior to TMD treatment in patients admitted to the DEPeI UNAM Physiology Laboratory during the period from August to December 2020.

o Record the neuromuscular electrical activity (RMS) and muscle fatigue (Hurst Index) of the masseter muscles of the three groups of patients with different treatments for TMD (GA = Transcutaneous electrostimulation and splint, GB = Percutaneous electrostimulation and splint, and GC = Occlusal

splint) by means of 6 electromyographic recordings scheduled weekly (T0 = Basal, T1 = 7 days, T2 = 14 days, T3 = 21 days, T4 = 28 days, T5 = 35 days, T6 = 42 days) in patients from the Laboratory Physiology of the DEPeI, UNAM, admitted during the period from August to December 2020.

o Record TMD signs and symptoms (muscle pain, joint pain, mouth opening limitation, presence of joint sounds and heart rate) during TMD treatments through 6 weekly scheduled evaluations (T0 = Baseline, T1 = 7 days , T2 = 14 days, T3 = 21 days, T4 = 28 days, T5 = 35 days, T6 = 42 days) in patients from the Physiology Laboratory of DEPeI, UNAM, admitted during the period from August to December 2020.

o Identify the changes in neuromuscular electrical activity (RMS) and muscle fatigue (Hurst Index) of the masseter muscles in each group (GA = Transcutaneous electrostimulation and splint, GB = percutaneous electrostimulation and splint, and CG = Occlusal splint) during the TMD treatment (T0 = Baseline, T1 = 7 days, T2 = 14 days, T3 = 21 days, T4 = 28 days, T5 = 35 days, T6 = 42 days) in patients from the Physiology Laboratory of DEPeI, UNAM, admitted during the period from August to December 2020.

o Compare the changes in neuromuscular electrical activity (RMS) and muscle fatigue (Hurst index) of the masseter muscles by group (GA = Transcutaneous electrostimulation and splint, GB = percutaneous electrostimulation and splint, and GC = Occlusal splint) during treatment of TMD (T0 = Basal, T1 = 7 days, T2 = 14 days, T3 = 21 days, T4 = 28 days, T5 = 35 days, T6 = 42 days) in patients from the DEPeI UNAM Physiology Laboratory, admitted during the period from August to December 2020.

o Identify the changes in TMD signs and symptoms (muscle pain, joint pain, limitation of mouth opening, presence of joint sounds and heart rate) in each group (GA = Transcutaneous electrostimulation and splint, GB = percutaneous electrostimulation and splint, and CG = Occlusal splint) during DTM treatment (T0 = Basal, T1 = 7 days, T2 = 14 days, T3 = 21 days, T4 = 28 days, T5 = 35 days, T6 = 42 days) in patients from the Laboratory of Physiology of the DEPeI UNAM, admitted during the period from August to December 2020. o Compare the changes in TMD signs and symptoms (muscle pain, joint pain, limitation of mouth opening, presence of joint sounds and heart rate) by group (GA = Transcutaneous electrostimulation and splint, GB = Percutaneous electrostimulation and splint, and CG = Occlusal splint) during DTM treatment (T0 = Baseline, T1 = 7 days, T2 = 14 days, T3 = 21 days, T4 = 28 days , T5 = 35 days, T6 = 42 days) in patients from the DEP Physiology Laboratory eI UNAM, admitted during the period from August to December 2020.

o Identify the changes in neuromuscular electrical activity (RMS) and muscle fatigue (Hurst Index) of the masseter muscles in each group (GA = Transcutaneous electrostimulation and splint, GB = percutaneous electrostimulation and splint, and CG = Occlusal splint) during the treatment of TMD according to the sociodemographic and clinical variables (age, sex, TMD, BMI, systemic diseases, use of prostheses, number of teeth present, drug intake), in patients from the DEPeI UNAM Physiology Laboratory, admitted during the period from August to December 2020.

o Compare the changes in neuromuscular electrical activity (RMS) and muscle fatigue (Hurst index) of the masseter muscles by group (GA = Transcutaneous electrostimulation and splint, GB =

percutaneous electrostimulation and splint, and GC = Occlusal splint) during treatment of TMD according to the sociodemographic and clinical variables (age, sex, TMD, BMI, systemic diseases, use of prostheses, number of teeth present, drug intake), in patients of the Physiology Laboratory of DEPeI, UNAM, admitted during the period from August to December 2020.

Hypothesis

Ha1: There will be a greater decrease in neuromuscular electrical activity (RMS) and muscle fatigue (Hurst index) of the masseter muscles in the treatment group with percutaneous electrostimulation (GB = percutaneous electrostimulation and splint) compared to the values of the electrostimulation groups transcutaneous (GA = transcutaneous electrostimulation and splint) and the control group (CG = Occlusal splint) of patients from the Physiology Laboratory of the Division of Postgraduate Studies and Research (DEPeI), UNAM, admitted during the period from August to December 2020 .

Ho1: There will be no decrease in neuromuscular electrical activity (RMS) and muscle fatigue (Hurst index) of the masseter muscles in the treatment group with percutaneous electrostimulation (GB = percutaneous electrostimulation and splint) compared to the values of the electrostimulation groups transcutaneous (GA = transcutaneous electrostimulation and splint) and the control group (CG = Occlusal splint) of patients from the Physiology Laboratory of the Division of Graduate Studies and Research (DEPeI) UNAM, admitted during the period from August to December 2020.

Material and methods

Type of study

Randomized clinical trial

Study population

Patients with TMD who will enter the Physiology Laboratory of the Division of Graduate Studies and Research (DEPeI) UNAM, during the period from August to December 2020.

The DEPeI UNAM Physiology Laboratory attends approximately 900 patients per year, of which 168 first-time patients are referred from other specialty clinics at DEPeI UNAM. Around 100 appointments are scheduled per month, most of them are for treatment controls through occlusal splint adjustment and electromyographic records. The patients received by the Physiology Laboratory are referred by the Reception and Diagnosis Clinic (Postgraduate), the specialty clinics of the DEPeI, stomatological services of hospitals and private clinics, among others.

Selection and sample size

The selection of the sample will be carried out by a convenience sampling which will be carried out based on the clinical evaluation (considering the inclusion and exclusion criteria) in patients with a diagnosis of TMD who will enter the DEPeI Physiology Laboratory during the period from August 2020 to December 2020.

The selected sample will be divided into three groups (GA = transcutaneous electrostimulation and splint, GB = percutaneous electrostimulation and splint, GC = splint); the allocation by group will be made by means of a randomization in balanced blocks. For this process, a series of blocks will be assembled made up of a certain number of cells in which the types of treatment are included. The number of blocks will be determined by the number of participants to be included in the study and the number of cells that it has been decided to include in each block. Each block will contain in each cell one of the treatment alternatives and within each block there must be a balanced number of possible treatments.

The recruitment period will be carried out during the period from August to December 2020, patients with a diagnosis of temporomandibular dysfunction (TMD) will be recruited who will enter the Physiology Laboratory of the Division of Postgraduate Studies and Research (DEPeI) UNAM, during the period from August to December 2020. The diagnosis of TMD will be carried out by the main researcher (Doctoral Student of the Master's and Doctoral Program in Dental and Health Medical Sciences) using the Diagnostic and Research Criteria for Temporomandibular Disorders (CDI / TTM) . (50) (Annex 1 and 2)

Sample size calculation

The characteristic analysis used to analyze the comparison of means in more than two groups corresponds to the one-way analysis of variance (ANOVA). (51) The sample size was estimated for ANOVA (Sample size For ANOVA).

Since the means are unknown, the background of the research is used: Camargo in 2018 (48), reports the electromyographic changes (RMS) of the trapezius muscles of four study groups with different treatments (G1 = superficial electro acupuncture, G2 = deep stimulation of trigger points, G3 = combination of acupuncture and electro acupuncture and G = 4 control group), before and after treatment.

For the sample size calculation, only the RMS values after the treatment used in groups 1, 2 and 4 were taken.

Electromyographic values (RMS) of the trapezius muscle of the three groups studied.		
Group 1 (Transcutaneous)	Group 2 (Percutaneous)	Control group
96.55µV.	85.38 µV.	86.82 µV.
87.45 µV.	65.37 µV.	80.25 µV.
92.51 µV.	95.1 µV.	83.02 µV.
84.31 µV.	74.11 µV.	74.99 µV.

DESCRIPTION					Alpha	0.05		
Group	*Count*	*Sum*	*Mean*	*Variance*	*SS*	*Std Err*	*Lower*	*Upper*
grupo 1	4	360.82	90.205	29.3043667	87.9131	4.30742221	80.460934	99.949066

grupo 2	4	319.96	79.99	168.561	505.683	4.30742221	70.245934	89.734066
grupo control	4	325.08	81.27	24.7812667	74.3438	4.30742221	71.525934	91.014066
ANOVA								
Sources	*SS*	*df*	*MS*	*F*	*P value*	*F crit*	*RMSSE*	*Omega Sq*
Between Gro	247.758467	2	123.879233	1.66918176	0.24178662	4.25649473	0.6459840	0.10033941
Within Groups	667.9399	9	74.2155444					
Total	915.698367	11	83.2453061					

Sample size calculation for three-group ANOVA.

The total sample size calculated for this study was 75.46 patients, 25 for each group. As it is a longitudinal study, losses are considered for the duration of treatment (6 weeks). An oversampling of the general n was estimated, increasing the n by 10%, having a final sample size of: n total = 84 patients in total n group = 28 patients in each group

Inclusion, exclusion and elimination criterio:

Inclusion criteria:

o Patients assigned to the DEPeI Physiology Laboratory admitted during the period from August to December 2020.

o Patients without prior TMD or TMD treatment o Patients in an age range between 18 to 60 years o Patients with permanent dentition o Patients with malocclusion o Patients with deviation when opening or closing the mandible o Patients with presence of articular noises in function

o Patients with myofascial or joint pain o Patients with prosthetic or implant treatments o Patients with partially edentulous arches o Bruxist patients

Exclusion criteria:

o Patients with periodontal problems o Patients with orthodontic treatment or use of dental braces o Patients with apparent neurological or sensory disabilities o Patients with bleeding disorders or with ingestion of anticoagulants o Patients with pacemakers, defibrillators or cardiac pathologies o Patients with epilepsy, thrombophlebitis, Active or uncontrolled phlebitis o Patients with the presence of facial wounds or severe acne o Patients with neurological or muscular disorders o Patients allergic to metal o Patients with infections or acute inflammatory processes o Pregnant patients o Patients with a history of joint surgery o Patients with malignancies o Patients with degenerative bone diseases o Patients with fibromyalgia o Patients with mental disorders

Elimination criteria:

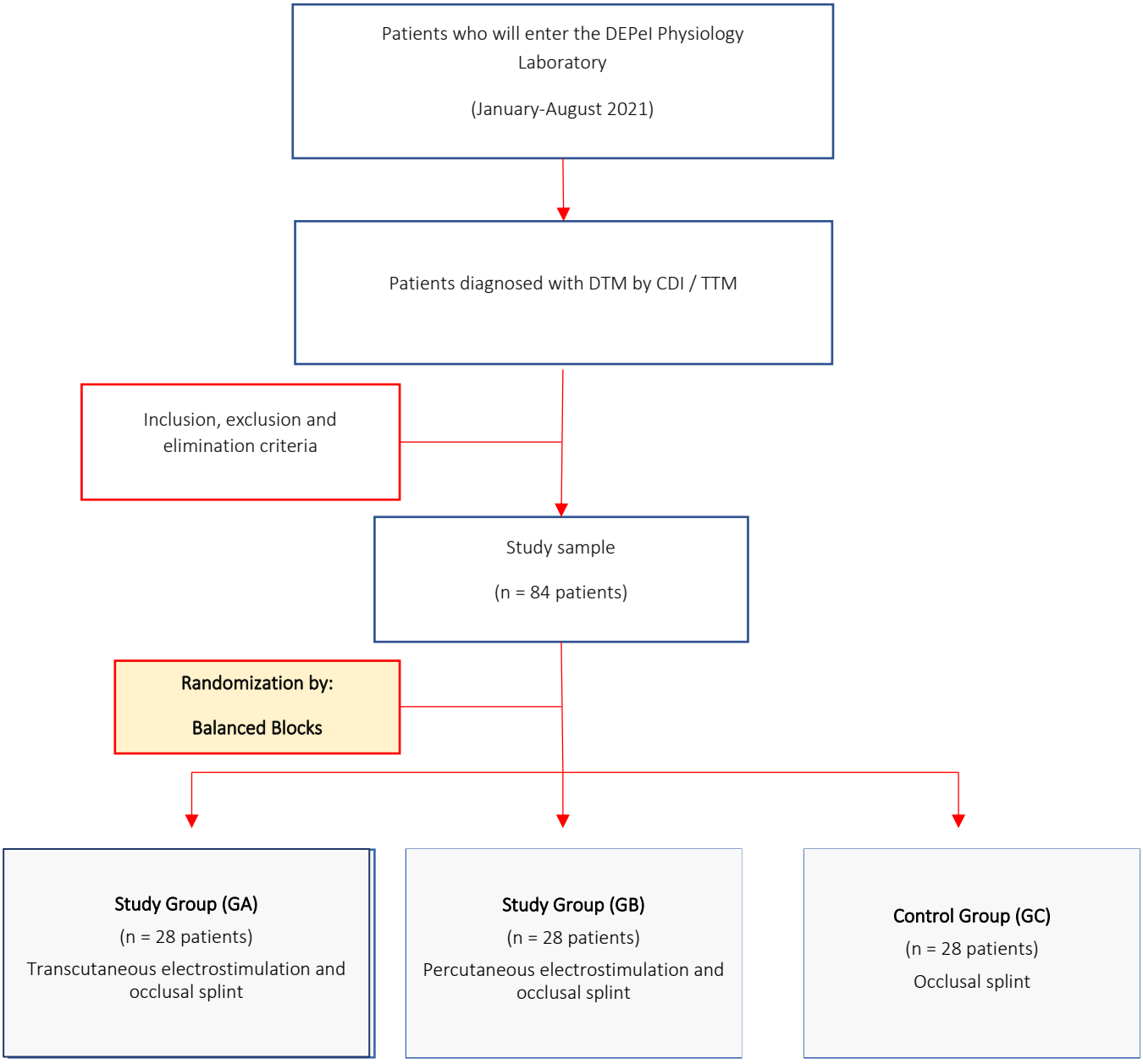
o Patients who do not wish to continue with electrostimulation therapies and / or the use of a splint.

o Patients who, during TMD treatment, require dental restorations or root canals.

o Patients who during TMD treatment suffer from some type of dental trauma or fracture.

Control group selection

The randomization of the total sample (84 patients) will be carried out to obtain the three study groups (28 patients per group) including the control group (CG = Occlusal splint).



Variables (identification, definition, measurement scale)

Sociodemographic variables		
Variable	Operational Definition	Measurement scale
Age	Years completed that the person indicates to have when making the medical history. ➢ Information obtained from the medical history	Number of years completed
Gender	Gender to which the person indicated in the medical history belongs. ➢ Observed during the medical history	1. Female 2. Male

Clinical variables		
Variable	Operational Definition	Measurement scale
Temporomandibular dysfunction (DTM)	Functional alteration of the temporomandibular joint that is identified by the presence of muscle or joint pain, joint sounds and restriction, deviation or deflection in the mandibular opening.	1. Muscle 2. Disc displacement 3. Arthralgia, arthritis, osteoarthritis
Body mass index (BMI)	Measure of obesity, where the mass is expressed in kilograms, and is divided by the square of the height in meters categorically determined based on the classification of nutritional status of the World Health Organization (WHO, 1990) ➢ Measurement estimated by measuring weight and height during clinical evaluation.	1. Under weight 2. Overweight 3. Obesity
Systemic diseases	Diagnosed systemic alteration that the patient responds to the question "Do you have any systemic disease?" when making the medical history. ➢ Information obtained from the medical history	1. Diabetes 2. Arterial hypertension 3. Rheumatoid arthritis 4. Diabetes and Hypertension
Drug intake	Taking medications prescribed by medical indication for some type of systemic alteration. ➢ Information obtained from the medical history	1. Not 2. Yes
Use of prosthetics	Use or presence of removable oral prosthesis at the time of clinical evaluation. ➢ Information obtained when conducting the clinical evaluation	1. Total upper arch prosthesis 2. Total lower arch prosthesis 3. Total prosthesis both arches 4. Removable partial upper arch prosthesis 5. Removable lower arch partial denture 6. Removable partial denture both arches

Number of teeth present	Number of teeth present in the mouth at the time of the clinical examination ➢ Information obtained when conducting the clinical evaluation	1. 1 to 8 teeth 2. 9 to 16 teeth 3. 17 to 24 teeth 4. 25 to 32 teeth
DTM Treatment	Type of therapy that the patient receives for 6 weeks for the treatment of DTM.	1. Transcutaneous electrostimulation therapy and occlusal splint 2. Percutaneous electrostimulation therapy and occlusal splint 3. Occlusal splint

Variables of signs and symptoms of DTM		
Variable	Definición operacional	Escala de medición
Muscle pain	Amount of muscular pain reported by the patient when applying a pressure of 1.5 Kg / cm2 in masseter muscles and 2.4 Kg / cm2 in temporal muscles using a circular tip of a Baseline brand pressure algometer. (52) ➢ Information obtained with visual analog scale when conducting the clinical evaluation.	0 to 10 Where 0 represents the absence of perceived pain, and 10 the maximum amount of pain
Joint pain	Amount of joint pain reported by the patient when applying a pressure of 1.5 Kg / cm2 to the surface area of the ATM using a circular tip of a baseline pressure algometer. (52) ➢ Information obtained with visual analog scale when conducting the clinical evaluation.	0 to 10 Where 0 represents the absence of perceived pain, and 10 the maximum amount of pain
Limitation of mouth opening	Amount of millimeters measured from the incisal edge of the upper anterior teeth to the incisal edge of the lower anterior teeth with a TeraBite ruler. ➢ Information obtained when conducting the clinical evaluation	Millimeters (mm) 1. Normal opening (> 40mm) 2. Opening limitation (<40mm.)
Presence of joint noises	Sound detected and recorded by the operator using a stethoscope placed in the anterior atrial area above the TMJ when making mandibular opening and closing movements. ➢ Information obtained when conducting the clinical evaluation	1) Not 2) Yes

Heart rate	Number of times the heart beats for one minute, measured with using a finger oximeter Pulox Oxímetro de Pulso PO-200 Information obtained when conducting the clinical evaluation	Number of beats Norm (60-100 beats)

Information gathering methods (selection of sources, methods, techniques and procedures):

Convenience samplings will be carried out, based on the evaluation of the clinical history, radiological studies (orthopantomography and comparative radiography of the TMJ open and closed mouth) and clinical examination, in patients of the Physiology Laboratory of the DEPeI UNAM, who will be admitted during the period from August to December 2020.

The diagnostic process of Temporomandibular Dysfunction (TMD) will be carried out by the Principal Investigator (Doctoral Student of the Master's and Doctoral Program in

Medical, Dental and Health Sciences) in patients who come to request service from the

Laboratory of Physiology of the Division of Postgraduate Studies and Research (DEPeI) of the School of Dentistry UNAM (UNAM) during the period from August to December 2020. Mtra. Claudia Ivonne Rodríguez Castañeda (Principal Investigator) carried out the calibration process for the diagnosis of temporomandibular disorders based on the diagnostic criteria of the American Dental Association, under the mentorship of Doctor Marcelo Kreiner at the Laboratory of Physiology of Dentistry of the University of the Republic, Uruguay. (Annexed 2)

The use of diagnostic criteria for the investigation of temporomandibular disorders (CDI / TMD) will be used (54). The instrument allows a physical examination and medical history in two axes. Axis I, based on a clinical examination divided into: a) muscular disorders b) disc displacements and, c) arthralgia, arthritis, osteoarthritis. The second axis comprises a questionnaire based on disabilities due to chronic pain and psychological aspects. (fifty)

Once the diagnosis is made, a protocolized algorithm is used for CDI / TMD scores (axis I and axis II) and thus determine the Diagnostic classification of TMD. (1.- muscular TMD, 2.- joint TMD, 3.- inflammatory TMD) (50)

After the diagnosis of TMD, a general clinical evaluation will be carried out to establish whether they meet the inclusion criteria, all patients who meet the characteristics described and who wish to participate in the study will sign an informed consent. After being included, a general, regional and local clinical examination will be carried out to collect baseline data for the study variables.

Data collection will be by primary technique and direct method through interviews (series of questions asked during the anamnesis for the complete record of the clinical history), observation (dental clinical evaluation) and digital surface electromyography, all carried out in a chair. at the DEPeI Physiology Laboratory, UNAM. This procedure will be performed by a previously trained and

standardized examiner and annotator (Cohen's Kappa 0.7), for a clearer performance of the clinical examination and the reduction of bias by the examiner for clinical methods. For the clinical examination, it will be performed in clockwise order, starting with the upper right quadrant. The first review will correspond to the presence of mixed dentition, use of prostheses, number of teeth, muscle pain (with a pressure algometer applying 1.5 kg / cm2 in masseter muscles, and 2.4 kg / cm2 in temporal muscles), joint pain (with algometer pressure applying 1.5 kg / cm2), presence of noises, limitation to mouth opening (with Terabite) and heart rate.

To assess pain by means of muscle and joint palpation with an algometer, the patient will be seated in a relaxed position, the evaluator will place the fine circular surface of the algometer perpendicular to the skin and an increasing pressure of 0.5 kg / cm2 will be applied increasing gradually over one minute until reaching 1.5 kg / cm2.

The patient will be instructed to verbalize the moment when pressure was exerted if a painful sensation was caused by muscle and in the joint area.

The treatment for TMD will be carried out by means of the conventional treatment with an occlusal splint and as an auxiliary method, transcutaneous and percutaneous electrostimulation therapies will be applied by the same operator during the period from August 2020 to June 2021. The appointments for clinical control for signs and symptoms of TMD , splint adjustment, electromyographic records and application of electrostimulation therapy as an adjunct to the use of splint, will be scheduled once a week in the Physiology Laboratory from 9:00 am to 1:00 pm and from 2:00 pm to 6:00 pm: 00pm for six consecutive weeks.

- Electromyographic recording technique

The registration system (hardware and software) that will be used for the electromyographic evaluation is the Electromyograph 1.2 UNAM-CINVESTAV, which consists of a two-channel system for the analysis of the electromyographic signal that offers greater precision and facilitates muscle assessment through the estimation made by the software of the RMS for its acronym in English (Root Mean Square) and Hurts Index. (53)

The RMS and Hurts Index will be recorded using three electrodes: one placed at the muscular origin, another at the insertion, and finally one in the behind-the-ear area as a ground or neutral electrode. The RMS recording is performed at maximum intercuspation for 30 seconds; the action potential that is expressed in electrical energy will be recorded in microvolts per second (µV / s).

6 electromyographic recordings will be performed on each patient (one record each week) during the time of splint use. Electromyographic recordings will be scheduled as well as follow-up control appointments, to make adjustments to the physiological occlusal splint.

Occlusal splint fabrication technique

The occlusal splints for the treatment of TMD will be the same for all the participants, they will be made by the Principal Investigator in the Physiology Laboratory of DEPeI, UNAM. The indications for the use of a splint and hygiene will be the same in all patients (the splint is worn 24 hours a day, it is

removed for eating and brushing teeth). The splint is washed with neutral liquid hand soap, no brushing or scrubbing).

To make the occlusal splint, an impression of the maxillary dental arches will be taken with alginate; the positive will be obtained with type IV stone plaster. Once the plaster has set, the models will be obtained to make the splint with a thermoplastic vacuum machine. A .060 "acetate sheet will be placed, and the second acetate will be a .080" caliber. Once the acetate sheet has been adapted to the working model, it will be cut with a carbide disk on the design previously made on the plaster model, marking the middle part of all the upper teeth on the buccal part to have the guide cutting. Surpluses will be removed with the help of a bur and polished to avoid damage to the soft tissues with a blanket wheel. Once this is done, he will test the patient to check that it does not generate any discomfort. Later it will be adjusted again to the working model to carry out the relining.

Relining is done with self-curing acrylic on the occlusal surface of the splint, leveling the amount of material on a glass tile. Then the occlusal adjustment is made with the help of articulating paper and thus achieve a homogeneous occlusal bite. Excess acrylic will be removed and placed back in the mouth to verify the dimension of the splint (interdental unocclusion), taking care that it does not interfere with any mandibular movement. It is finished by polishing the splint with the help of a blanket wheel and polyacril.

Transcutaneous electrical stimulation technique

The transcutaneous electrostimulation therapies will be carried out by the Principal Investigator, who will be trained in the ISSSTE Clinic Specialties East Leonardo Bravo Complex in the acupuncture service under the supervision of Dr. Roberto Sánchez Ahedo. (Surgeon, Specialist in Family Medicine. Training in acupuncture in different institutions. Master's in Medical Education, Doctorate in Education, Professor of various courses in acupuncture from a medical perspective. Academic of the Faculty of Medicine of UNAM.)

For transcutaneous electro stimulation therapy, Kendall® MediTrace 100 conductive adhesive ECG electrodes (pediatric) with a diameter of 2.4 cm, and portable electro-stimulator equipment KWD-808 (professional equipment for electroacupuncture and rehabilitation) will be used.

The patient will be positioned on the dental chair, the superficial area of the skin of the masseter muscle will be cleaned with alcohol and cotton. Two Kendall® MediTrace 100 electrodes will be placed in each masseter muscle (right and left), considering the same references that were used for the electrodes placed for the electromyographic recording; the first electrode is placed at the origin of the masseter muscle or superficial area of the mandibular condyle and the second at the insertion of the masseter muscle at the angle of the mandible. After placing the electrodes, the KWD-808 electroacupuncture device will be connected to the patient by means of two double alligator cables; the alligators will be pressed to the metal head of each electrode: the positive pole (red color) will be connected at the origin of the masseter muscle and the negative pole (black color) at the insertion of the masseter muscle.

Before nerve stimulation, all patients will be informed of the perceived sensation, which in some patients will range from imperceptible to barely noticeable or not very noticeable.

The parameters to be used will be: pulse duration until sensory activation and high intensities, but with an established limit to prevent muscle contraction and that allows maximum comfort for 20 minutes. Current will be transmitted with square or rectangular waveform, the stimulation frequency: two frequency bands (low: 210Hz and high 10140Hz.); wave amplitude: 3050 volts, pulse duration: 40100 msec; and the output intensity: 0.70 (for 100Hz). The treatment time will be 20 minutes; the equipment has the quality of timing itself and after time it will stop transmitting a signal to the patient. The treatment will consist of the application of six consecutive therapies programs weekly.

Percutaneous electrical stimulation technique

The transcutaneous electrostimulation therapies will be carried out by the Principal Investigator, who will be trained in the ISSSTE Clinic Specialties East Leonardo Bravo Complex in the acupuncture service under the supervision of Dr. Roberto Sánchez Ahedo. (Surgeon, Specialist in Family Medicine. Training in acupuncture in different institutions. Master's in Medical Education, Doctorate in Education, Professor of various courses in acupuncture from a medical perspective. Academic of the Faculty of Medicine of UNAM.)

For percutaneous electrostimulation therapies, sterile steel acupuncture needles of 0.25x13mm, disposable AcuBEST brand (FDA 510K), and portable electrostimulator equipment KWD-808 (professional equipment for electroacupuncture and rehabilitation) will be used.

Prior to the placement of therapy, the superficial area of the skin of the masseter muscle will be cleaned with alcohol and cotton. The puncture technique will be carried out by taking the needle through the body (not by the handle), the lower part is held between the thumb and index finger of the right hand, allowing the tip of the needle to pass. Directing the needle to the acupuncture point to insert it quickly (penetrating 5 mm).

Two needles will be placed in the right masseter muscle and two in the left masseter muscle each at the reference trigger points (local TMD points), following the

"Practical recommendations for the treatment of Temporomandibular Disorders" (55); the area to be punctured is the origin of the masseter muscle or superficial area of the mandibular condyle anterior to the atrial tragus approximately 1cm away (proximal acupuncture points: Gb3, Si 19, Gb 2, St 7), insertion of the masseter muscle at the angle of the mandible (Proximal acupuncture points: St6, St5). For this study, distal stitches will not be placed.

After placing the needles, the KWD-808 electroacupuncture device will be connected to the patient; The two double alligator cables will be connected to each patient by means of the alligators that will directly press the head of the needles. The positive pole (red color) will be connected at the origin of the masseter muscle and the negative pole (black color) will be placed at the insertion of the masseter muscle.

Before nerve stimulation, all patients will be informed of the perceived sensation, which in some patients will range from imperceptible to barely noticeable or not very noticeable.

The parameters to be used will be: pulse duration until sensory activation and high intensities, but with an established limit to prevent muscle contraction and that allows maximum comfort for 20 minutes. Current will be transmitted with square or rectangular waveform, the stimulation frequency: two frequency bands (low: 210Hz and high 10140Hz.); wave amplitude: 3050 volts, pulse duration: 40100 msec; and the output intensity: 0.70 (for 100Hz). The treatment time will be 20 minutes: The equipment has the quality of timing itself and after time it will stop transmitting a signal to the patient.

The treatment will be carried out every week with a total of six continuous therapies or if the patient deserves it until the remission of symptoms.

Pilot test

A pilot test of transcutaneous and percutaneous electrical stimulation therapies will be carried out in a selection of 8 patients who wish to participate in the study at the DEPeI Physiology Laboratory. The appropriate placement of the points to be stimulated during therapy, the patient preparation time for therapy, the clinical examination to collect the independent variables, and the electromyographic recording method will be identified.

The electromyography will identify the RMS and Hurts Index values of each recording and the changes in the electrical activity of the masseter muscles will be evaluated during electrostimulation and splint appointments. The criteria for the electromyographic recording method and its duration (30 seconds, measured in microvolts (μV)) will be evaluated.

Processing record methods

The registration of data processing will be carried out in two stages:

• During the first stage, the information obtained with respect to the variables of interest will be recorded in the Clinical History of the Physiology Laboratory of each patient, which will be filled out during the clinical evaluation, electrostimulation therapies and electromyographic record in maximum intercuspation.

• In the second stage, the database will be created, transferring the data recorded in the Information Collection Instruments format for each patient to an Excel spreadsheet, to later perform the statistical analysis in the statistical software Stata version 14.

Statistical data analysis plan

o A descriptive analysis of the main clinical characteristics of the population studied will be carried out in the case of continuous variables, the mean and standard deviation or the median and its interquartile range will be reported according to its distribution normal and antagonistic as n and percentage (%).

o The muscle effect of electrostimulation therapies within and between groups over time (before and during the 6 weeks of treatment), will be calculated using two-way ANOVA for repeated measures. Furthermore, the significant effect size of the comparison is calculated according to Cohen's effects (small (0.20), moderate (0.50) and large (0.80)).

o To identify the changes in the electromyographic activity of the multifractal analysis (Hurts Index and RMS) recorded by time of the right and left masseter muscles of all subjects, since each subject will be evaluated in 6 instances weekly, multilevel models will be adjusted (56) to describe the effect of the passage of time (T0 = Baseline, T1 = 7 days, T2 = 14 days, T3 = 21 days, T4 = 28 days, T5 = 35 days,

T6 = 42 days) of splint use and electrostimulation therapy and the effect of different explanatory variables on this change as on the initial value.

o All statistical calculations will be carried out in Stata 14 software (StataCorp., 2015).

Organization

a) Human resources

Tutor: Dr. Fernando Ángeles Medina

Tutorial Committee: Dra. Aida Borges Yáñez and Dr. Eduardo LLamosas Hernández

Operator: Mtra. Claudia Ivonne Rodríguez Castañeda

External advisors: Dr. Marcelo Kreiner and Dr. Roberto Sánchez Ahedo

b) Material resources:

EQUIPOS	INSTRUMENTAL	MATERIAL	STATIONERY
(1) Unidad odontológica (1) Electroestimulador de presión "Baseline" (1) Electromiógrafo digital CINVESTAV-UNAM (1) Electroestimulador KWD-808 (1) Computadora (1) Impresora (1) Cámara fotográfica	(10) Diagnostic equipment (mirror, caliper, scanner) (3) Therbite (2) Algometer (100) Slay Tongues	(50) (25 packs) Kendall® Electrodes (50) (10 packs) Acupoint® needles 0.025mm x 25mm (65) (2 boxes) Manhole covers (4 boxes) Gloves (5) Aerosol disinfectant (3 packs) Gauze (1) Alcohol (2 packs) Cotton	(50) Medical record formats - Laboratory of Physiology (50) Informed consent forms (50) Data collection sheets

c) Research development stages:

I. Training stage:

During the first, a review of the literature will be carried out and the methods of applying the therapies will be described.

The training process for the application of electrostimulation therapies will be completed based on the WHO Guidelines established in the Official Mexican NOM-172-SSA1-1998, which specifies the operating criteria for the practice of human acupuncture and related methods (electrostimulation therapies). The Standard governs that the training of a Physician or Health Personnel to fully exercise these therapies requires training of at least 350 academic hours. For this reason, the main researcher will complete during this stage the theoretical, practical and clinical preparation course taught by the UNAM Faculty of Medicine "Diploma in Complementary Medicine and

Acupuncture "with a total of 450 academic hours lasting one year (August 2019-September 2020), to comply with the basic training and training guidelines for the application of electrostimulation therapies.

The pilot test of transcutaneous and percutaneous electrostimulation therapies will be carried out in 8 patients from the Physiology Laboratory.

The recruitment phase of the sample will be carried out by evaluating the patients, the TMD diagnostic process and the evaluation of inclusion criteria who attend the Physiology Laboratory of the DEPeI UNAM during the period from August to December 2020. The randomization will be carried out of patients recruited during this period.

II. Clinical stage

The sociodemographic, clinical, signs and symptoms of TMD and neuromuscular variables of the patients will be measured and recorded.

Occlusal splints will be made to start with TMD treatments

Transcutaneous and percutaneous electrostimulation therapies will be applied

Scheduled electromyographic recordings will be performed weekly for a period of 6 weeks.

III. Results analysis stage

The database and statistical analysis of the results will be carried out

Knowledge dissemination exercises (Article writing)

BUDGET

PAPIIT IT201320 project

a*) Ethical aspects:*

In accordance with article 17 of the regulation of the General Health Law on Health Research (SS) in its second title, this project is considered Research with a risk greater than the minimum: since they are considered: radiological studies and with microwaves and modalities that are defined in article 65 of these Regulations, trials with new devices, procedures that use random methods of assignment to therapeutic schemes, for which the signing of informed consent will be essential.

The protocol will be submitted to the Research and Ethics Committee of the UNAM School of Dentistry for approval.

The clinical methodology for the application of the therapies Transcutaneous electrical nerve stimulation and Percutaneous Neuromodulation Therapy will be carried out based on:

• OFFICIAL MEXICAN STANDARD NOM-017-SSA3-2012. Regulation of health services for the practice of human acupuncture and related methods.

• Official Mexican STANDARD NOM-197-SSA1-2000. That establishes the minimum infrastructure and equipment requirements for hospitals and specialized medical care offices.

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