EFFECTIVENESS OF PRESSURE RELEASE TECHNIQUE BY TRIGGER POINT OF THE MASTICATORY AND CERVICAL MUSCLES IN PATIENTS WITH CHRONIC MYOFASCIAL TEMPOROMANDIBULAR DYSFUNCTION.

Promoter protocol code: 154/105-E

Version / Date: 03/16/2015

CLINICAL TRIAL PROTOCOL

1. IDENTIFICATION OF THE PROTOCOL

_ Promoter protocol code (IRB): 154/105-E

_ Version / Date: 03/16/2015

2. TITLE OF THE CLINICAL TRIAL

"Effectiveness of pressure release technique by trigger point of the masticatory and cervical muscles in patients with chronic myofascial temporomandibular dysfunction. "

3. IDENTIFICATION OF THE PROMOTER

Dª Gema Serrano Hernanz. Physiotherapist. Master in research in Health care. PhD candidate in the Health care program of the Faculty of Nursing, Physiotherapy and Podiatry of the University Complutense of Madrid. Collaborate Professor of the Title of Specialist of temporomandibular disorders and orofacial pain of the Faculty of Dentistry from the Complutense University of Madrid.

4. RELEVANT ASPECTS ON THE FINANCING OF THE STUDY

There is no financing. It is part of the doctoral program of the UCM.

5. CENTERS WHERE THE TRIAL IS EXPECTED TO BE PERFORMED

The trial will be conducted in the Rehabilitation and Electromyography Service of the Dentistry Faculty and Nursery Faculty of University Complutense of Madrid, and the Health Faculty of Aarhus University

6. JUSTIFICATIONS AND RELEVANCE OF THE STUDY

- Justification of the study:

The management of patients with myofascial temporomandibular dysfunction is usually attended by dentists independently to others disciplines by oclusal splint or discharge, without taking into account other adjunctive therapeutic possibilities, that is why it is described in this study the therapeutic alternative that represents physiotherapy in pain of myofascial TMD. The reality is that the treatments offered tend to produce small effects, often only in the short term and none seems to effectively change the long-term forecast. There is an almost endless list of options of treatment currently available for patients with orofacial pain, each supported by different theories and supported by research other disciplines. The collaboration between different disciplines means an

improvement of the quality of care that has a positive effect on the patient, making possible normalization of muscle activity and myofascial pain orofacial.

- Description of current knowledge of the problem in question:

Given the studies of recent years on the effectiveness of treatments for Myofascial Pain in TMD and the Evidence of the conclusions, it can be considered that the treatment by splint oclusal meets more consensus but is insufficient in the approach to complexity of myofascial pain. We have to face three aspects involved in the recovery of myofascial pain:

- Weakness of the local musculature.
- Myofascial trigger points TrPs.
- Psychosocial behaviours that may favour perpetuation.
- Contribution of the essay in relation to what is already known:

It is proposed to act on each of these aspects from the physiotherapy through:

- Myofascial release by trigger point pressure: affects the TrPs in a way that facilitates the realization of movements to reduce pain Myofascial and regulate muscle tone.

7. DESIGN

- The trial will be carried out in the Rehabilitation and Electromyography Service of the Department of Prosthesis I of the Faculty of Dentistry. University Complutense of Madrid.
- Confidentiality: The processing, communication and transfer of data of the personal nature of all the participating subjects will be in accordance with the in Organic Law 15/1999, of December 13, protection of data of personal character. The data will be included in a Research File; the responsible person will be the principal investigator, Dª Gema Serrano Hernanz.

The data collected for the study will be identified through a code

- It will be from parallel groups.
- Methods of random assignment, including the technique used to ensure the integrity of the allocation process:

Each participant will be identified by an identification code, assigned to the control and experimental groups, alternately and in order of inclusion in the study.

- Type of control: active.
- Form of masking: simple blind.

8. MAIN GOAL

- Check the effectiveness of the pressure release technique of the trigger points in the treatment of myofascial pain TMD. It is assessed using the EVA and algometry scale.

Secondary objectives.

- Assess the effectiveness of pressure release technique through the parameters of: mouth opening, stress / anxiety, catastrophizing, kinesiofobia and cervical disability.

9. THERAPEUTIC GROUPS.

Two groups are established:

- Group A: intervention group: myofascial release treatment by trigger point pressure combined with dental treatment (oclusal splint and self-care).
- Group B: control group: placebo combined with dental treatment (oclusal splint and self-care).

Intervention protocol.

- Myofascial release treatment by trigger point pressure: 5 sessions, one per week.

Pressure release technique:

It will consist of pressure with the thumb and / or index normally gradual, deep and maintained 90 sec, of the muscles: deep and superficial masseters; anterior, medial and posterior temporalis; sternal and claviclar sternocleidomastoid and upper trapezius.

- Odontology treatment: oclusal splint and self-care.
- Placebo: simulation of the pressure release technique of the trigger points without executing it:

Pressure release Technique:

It will make the same contacts without pressure, and therefore will eliminate the myofascial trigger points of the muscles: deep and superficial masseters; anterior, medial and posterior temporalis; sternal and claviclar sternocleidomastoid and upper trapezius.

Periodicity of the evaluation: measurements will be made:

- At the beginning of the study.
- At 5 weeks, end of treatment.
- At 3 months from the end of the intervention.

10. MAIN VARIABLE VALUATION. SECONDARY VARIABLES

- Pain is assessed using the EVA scale.
- Other variables: algometry, kinesiofobia, catastrophizing, anxiety, stress, mouth opening and cervical disability.

11. POPULATION IN STUDY AND TOTAL NUMBER OF PATIENTS

· Estimation of the sample size:

Considering the main objective of the study is to compare two independent means and what it want to achieve:

H0: μA = μB. Null hypothesis: the effectiveness of pressure release technique of trigger points of the masticatory and cervical muscles have no effect.

H1: μA ≠ μB. Alternative hypothesis: there are differences between the efficacy of pressure release technique by trigger point of the masticatory and cervical muscles and conventional treatment.

- Significance level: α = 0.05
- Power: 1-β = 0.80
- Type of bilateral contrast.
- Loss of patients = 10%
- Clinically relevant difference = 2

It is estimated that 35 subjects are needed in each sample group. Total 70 subjects.

- Target population:

All patients with myofascial TMD who are referred to the Rehabilitation and Electromyography Service of the Faculty of Dentistry of the UCM.

- Study population.

Target population that meets the inclusion criteria and does not have criteria for exclusion.

1. Inclusion criteria.

- Patients diagnosed with myofascial TMD.
- Age between 20-60 years.
- Myofascial TMD greater than 6 months of evolution.

2. Exclusion criteria.

· Patients diagnosed with neoplasia, fractures, rheumatoid arthritis, surgery.

. Patients with motor and sensory deficits of N. Trigeminal V.

. Patients with psychiatric and/or cognitive disorders.

Recruitment: Chronic patients who have gone through different phases of treatment and turn to the specialized service provided by the Faculty of Odontology of the UCM, advised on occasion by your dentist / doctor reference.

12. STATISTICAL ANALYSIS

Descriptive statistics and inference with all the evaluable data.

13. ETHICAL CONSIDERATIONS

• Evaluation of the benefit / risk: The benefit that could be obtained from the results of the study is an improvement of the symptoms that allow progress in the overall improvement of the patient, and develop education in the self-care The risks or inconveniences are minimal compared to the expected profit.

• The patient information sheet and informed consent will be provided and All questions raised by potential participants will be addressed.

• Direct access to data. Monitoring, audits, CEIC reviews and regulatory inspections related to the trial, facilitating direct access to original documents / data.

• The choice of control treatment to achieve the objective of the study: motor control exercises are considered an essential requirement for a long-term recovery and is the basis of any treatment complementary.

14. DURATION OF THE TREATMENT.

Duration of 5 weeks from the beginning to the end of the follow-up, in which the participant is part of the study

18. CALENDAR AND ESTIMATED FINISHING DATE

It will start immediately after obtaining the CEIC permit and it will end according to schedule.

INFORMED CONSENT FORM

Title of the Research Project: "Effectiveness of pressure release technique by trigger point of the masticatory and cervical muscles in patients with chronic myofascial temporomandibular dysfunction".

Promoter: Dª Gema Serrano Hernanz.

Me, (first and last name) ....
I have read the information sheet that has been entered.
I have ask questions about the study.
I have received enough information about the study.
I have spoken with Dª Gema Serrano Hernanz.
I understand that my participation is voluntary.
I understand that I can withdraw from the study:

- 1st When you want
- 2nd Without having to explain.
- 3rd Without this having an impact on my medical care.

I freely give my consent to participate in the study.

SIGNATURE OF THE PARTICIPANT

SIGNATURE OF THE INVESTIGATOR

DATE: