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RESEARCH PROJECT

Dry Needling and Photobiomodulation in the treatment of Myofascial Pain

Study Principal Investigator: Rafael Inácio Barbosa, PhD.

ABSTRACT

Myofascial Pain is a clinical condition of myalgic pain characterized mainly by the presence of Myofascial Trigger Points. Trigger points can be active or latent and they are described as a hypersensitive spot within a taut band in the muscle. The use of a computer for long periods has been shown as a trigger the trigger points. Dry Needling and Low-Level Laser Therapy (LLLT) has been described as good resources to treat myofascial pain. The hypothesis is that the association of the purposed interventions will have greater effects than only the dry needling intervention. The objective is to evaluate the effects of the dry needling and the laser in the treatment of upper trapezius trigger point on women. This study is composed of an evaluation and an intervention proposal with dry needling and LLLT to treat myofascial trigger points. The sample will be composed of 60 women, with 18 to 65 years old, divided into three groups. Twenty individuals will be in group Dry-On that will receive dry needling intervention on the trigger point, followed by LLLT intervention on. Twenty individuals will be in group Dry-Off that will receive dry needling intervention on the trigger point, followed by LLLT intervention turned off. Twenty individuals will be in group Control that will receive dry needling intervention at 1.5 cm from the trigger point, followed by LLLT intervention turned off. All interventions will be performed in one session. Outcome measures for pain, pressure pain threshold, functionality, and muscle activity will be collected.

Key-words: Myofascial pain; Pressure Pain Threshold; Low-Level Laser Therapy; Dry needling;

1. INTRODUCTION

The International Association for the Study of Pain (IASP) defines pain as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage” (1). The Myofascial Pain is the clinical condition where the patient presents regional muscle pain, and that is characterized by the presence of symptomatic trigger points in one or more sites, which can be associated to local or referred pain, muscle spasms, increase in sensibility, stiffness, muscle weakness, decrease in range of motion, and autonomic dysfunction (2,3).

Women are the most affected by myofascial pain. It may be explained once women have lower pain pressure threshold (PPT) compared to men, which means higher hypersensitivity to mechanical stimulation (4). Moreover, both gender also has differences in electromyographic findings when induced to muscle pain, suggesting that women have a mechanism of protector adaptation less efficient to pain stimulation than men’s protector mechanism (5).

According to Simons & Travell (6), the myofascial trigger point is a hyperirritable spot, hypersensitive nodule palpable inside of a tender band that is painful on compression and that can give rise to referred pain, tenderness, and autonomic phenomena. This palpable nodule is usually located in hyperalgesic areas inside muscle, ligaments, and tendons, and it is associated with several conditions of chronic pain (2,7,8). The trigger points are classified as active and latent, where active trigger points have spontaneous local pain and referred pain away from the trigger point spot. The latent trigger point demonstrates pain only when stimulated with mechanical pressure, what can evoke local and/or referred pain without spontaneous pain (7).

Several studies have shown a variety of therapeutic resources that can be used in the treatment of trigger points and the myofascial pain, as: lidocaine injection (3,9), exercise and stretching (10), dry needling (7,11,12), photobiomodulation (13), therapeutic ultrasound (14,15) and ischemic compression (16).

The dry needling technic has been growing and gaining space among physical therapists as an option to treat myofascial pain and trigger points (7). The technic is described as an intervention where a fine, solid and filiform needle is inserted through the skin to stimulate trigger points, muscle and connective tissue to modulate neuromusculoskeletal pain and movement limitation (2,17). One mode of dry needling application is the fast-in and fast-out

technique developed by Hong, which consists in moving the needle up and down during approximately 30 seconds or until the local twitch response disappears (9,18).

Clinical trials using the dry needling technique in trigger points on upper and lower trapezius demonstrate improvement in pain, increase of PPT and on neck pain questionnaires scores, and an increase of cervical range of motion (ROM) compared with groups where the dry needling was applied away from the trigger point or that do not receive intervention (19,20). Espejo-Antúnez et al (12), in 2017, concluded in their systematic review that the dry needling can result in positive effects at short-term on pain, the range of motion, and quality of life when compared to placebo groups or groups without intervention; and it has similar effects to pharmacological intervention.

Photobiomodulation resources, like Low-Level Laser Therapy (LLLT), have been studied as a resource to treat trigger points and myofascial pain. Ilbuldu et al (13), in 2004, verified that the LLLT has an effect on the treatment of upper trapezius trigger point by decreasing pain, increasing pain pressure threshold, increasing the cervical range of motion, and improving functional activities before 4 weeks of intervention. The treatment was performed 3 times per week for 4 weeks and used a He-Ne laser equipment, 632.8 nm, 2J of energy. Uemoto et al. (21), in 2013, used a dose of 4 J/cm²m wavelength of 795nm, 80mW, on masseter trigger points and they find positive results to inhibit trigger point, improve pain and increase PPT.

These effects can be explained on the red light spectrum, near to infrared (660nm-905nm), have good effects to reduce inflammation, relieve pain, and accelerate the tissue regeneration (22). According to Gerwin (4), 2010, the LLLT has level B of the recommendation of probable effect on the treatment of pain caused by myofascial trigger points. Gattie et al (23), 2017, in their systematic review, state that the current information on dry needling intervention, whether compared to placebo treatment or when compared to another intervention, has very low to moderate quality of evidence. Furthermore, although the trigger points demonstrate changes in muscle activation obtained through electromyography (EMG), there are few studies that present EMG findings in order to demonstrate the effects of dry needling directly on muscle activity (24,25)

In this context, the present study aims to answer if the association of dry needling and photobiomodulation will have a greater effect on the treatment of myofascial trigger points than the dry needling alone or the placebo treatment.

2. OBJECTIVES

2.1. General Objective

The present study has the objective to evaluate the effects of dry needling and photobiomodulation application in the treatment of trigger points in upper trapezius on women with myofascial pain.

2.2. Specific Objectives

To evaluate the pain level before, during, and after the dry needling and photobiomodulation applications on the trigger point.

To identify the pain pressure threshold before and after dry needling and photobiomodulation applications on the trigger point

To verify the electromyographic activity of upper trapezius before and after the proposed treatments

To compare the effects fond intra and inter-groups for the applications of dry needling, dry needling and photobiomodulation, and control protocol.

3. METHODS

3.1. Study Design

The present study is characterized as a randomized clinical trial, controlled, with a proposal of evaluation and intervention of dry needling associated to the low-level laser therapy (LLLT) to treat the trigger point caused by myofascial pain. The subjects will be randomized into three groups:

- Group On: application of dry needling and LLLT turned on directly on the trigger point;
- Group Off: application of dry needling and LLLT turned off directly on the trigger point;
- Placebo/Control group: application of dry needling and LLLT turned off away from the trigger point.

3.2. Local of the Study

The study will be performed at the Laboratory of Evaluation and Rehabilitation of the Locomotor Apparatus (LARAL), located at Universidade Federal de Santa Catarina, Campus Araranguá, Santa Catarina, Brazil.

3.3. Subjects

Women, with age between 18 and 65 years old, students, workers, and professors at Universidade Federal de Santa Catarina (UFSC) will be invited to participate in the research.

The invitation of subjects to participate in the study will be done through digital and printed folders that will be delivered at UFSC and on the social media. Those subjects that show interest to participate will be forwarded to an evaluation selection where it will be identified if the participant fits the inclusion criteria and where the Consent Form will be presented.

The sample will be composed by 20 subjects in each group, a total of 60 subjects, according to a convenience sample based on review studies of Cagnie et al., 2015(26), and Espejo-Antúnez et al., 2017 (12).

3.3.1. Inclusion Criteria

- Presence of active trigger point in upper trapezius.
- Use of computer for typing activities for, at least, 20 hours per week.
- Presence of mechanic pain in cervical region for less than three months.
- Pain level higher than 3 and lower than 8 on the Visual Analogue Scale (VAS) for neck and cervical regions in the last 30 days.

3.3.2. Exclusion Criteria

- Body Mass Index (BMI) higher than 30
- Presence of whiplash injury or other cervical pathologies such as herniated disc and Thoracic Gorge Syndrome;
- Presence of contraindication to the treatment with low-level laser therapy or with dry needling
- Fear of needles
- To be receiving treatment for the pain in neck and/or shoulder regions
- Make use of analgesic drugs, anti-inflammatory and/or muscle relaxants and anticoagulant medications.

3.4. Evaluation procedures

The active trigger point in upper trapezius will be localized through manual palpation and the location will be marked with a special pen for the skin. A second mark located 1.5 centimeters medially from the trigger point will be made in all subjects. The trigger point identification will follow Simons et al. (6,27) criteria, featuring 3 of 4 items: (1) presence of

palpable taut band in the muscle; (2) presence of hypersensitive spot inside the taut band; (3) subject recognize the familiar pain; and (4) painful limitation of the range of motion during total stretch.

The surface electromyography (EMG) will be used to evaluate the muscle recruitment pattern. It will be used the equipment Miotec® (Miotool 400, Software Miograph®), with analog to digital (A/D) converter of 14 bits of resolution, amplified acquisition in 2000 Hz, common rejection mode of 100 dB, and band-pass filter set between 10-500 Hz. Disposable electrodes, made with polyethylene foam and with hypoallergenic adhesive, solid gel adherent, bipolar contact of Ag/AgCl (silver/silver chloride), will be used and positioned with 20mm of distance between poles. The Medtrace® reference electrode will be positioned in the ipsilateral wrist of the data collection. The electrodes will be positioned in the upper trapezius muscle as recommended by SENIAM (Surface ElectroMyoGraphy for the Non-Invasive Assessment of Muscles).

The skin where the electrodes will be positioned will be prepared according to SENIAM recommendation. It will be performed the removal of local hairs with the aid of a disposable razor and the skin will be slight exfoliated with dermatological sandpaper. The process of skin preparation will be finished with the use of a cotton moistened with 70% alcohol on the site with the purpose of reducing the electrical impedance of the skin for the posterior capture of EMG signals (28). The subject will be asked to perform a shoulder abduction of 90°, without additional load and with the hand facing down, and maintain this position for 15 seconds. This movement will be repeated four times, with 30 seconds of rest interval (24,29). For data analysis will be used the Root Mean Square (RMS) and Medium Frequency (FMed) data in microvolts and Hertz, respectively.

The Visual Analogue Scale (VAS) will be used so the subjects can graduate their pain in shoulder and neck regions. The VAS level of pain will be acquired before the intervention (baseline), soon after the intervention (T₁), 30 minutes after the intervention (T₂), one week (T₃) and one month (T₄) after the intervention.

Pressure algometry will be used to evaluate the pain pressure threshold (PPT). This measured will be obtained before the intervention (baseline), soon after the intervention (T₁), and 30 minutes after the intervention (T₂). The equipment will be positioned on the trigger point mark and the subject will be instructed to report when the sensation changes from pressure to pain (16). The force measured in kilograms per square centimeter (kg / cm²) will correspond to

the quantity of pressure needed so the subject report change in pressure pain sensation (14). The pressure will increase constantly on 1 kg / cm² / s. It will be collected three measured, with an interval of 20 seconds between each measure, and the average of the three values will be used in data analysis.

The Neck Disability Index (NDI) is a unidimensional questionnaire composed of 10 items that have the aim to evaluate the limitation caused by pain and disability on the neck (30). This questionnaire is organized according to the type of activity performed and express positive levels of functional capability. Its score ranges from 0 to 50, where 0 to 4 is considered total capacity, 5 to 14 is mild incapacity, 15 to 24 is moderate incapacity, 25 to 34 is serious incapacity, and >35 is severe incapacity. The questionnaire will be self-applied and the subject will answer it before the intervention, one week and one month after intervention.

3.5. Intervention Protocols

3.5.1. Dry needling protocol

The Dry Needling (DN) protocol will be performed in one session. It will be used acupuncture needles, individually packaged and sterilized, with 0.25 mm of thickness and 0.40 mm of length. Before the intervention, the skin will be clean with 70% alcohol. The therapist, then, will perform the grip in upper trapezius on the site of one of the two previously marked locations, according to the subject group allocation, and will insert the needle in the skin with help of a guide tube and will deepen the needle approximately 10 to 15 mm inside the trigger point (31).

The needle will be moved up and down as in the “fast-in and fast-out” technique described by Hong (18). The movement will be repeated during 30 seconds in a cadence of approximately 1 Hz (31). Once the study of Perreault, Dunning & Butts (32), in 2017, demonstrated that there is no need to seek the local twitch response to the DN have an effect, we do not have the aim to seek such response to the stimulus. The protocol will be the same for the groups that will receive the application directly on the trigger point and for the group that will receive the application away from the trigger point.

3.5.2. Photobiomodulation protocol

The photobiomodulation protocol will be performed using an equipment from Ibramed Equipamentos Médicos® of Aluminized Gallium Arsenide (AsGaAl) laser diode, with a wavelength of 830 nm, fluency of 20 J/cm², 30 mW, beam area of 0.116 cm², energy of 2,3 J

per point, continuous beam (22). The low-level laser therapy (LLLT) will be applied for 30 seconds at one point on the trigger point in upper trapezius, right after the dry needling application.

3.5.3. Placebo protocol

The placebo/control group will receive the DN application 1.5 cm away from the trigger point and will follow the application protocol described above. The LLLT equipment will be turned off during the intervention. As the other groups, it will be performed one session of the dry needling followed by the intervention with the laser turned off.

3.6. Statistical Analysis

Data analysis will be performed through the GraphPad Prism[®] software, version 6.01 (GraphPad Software, La Jolla, California, USA). The Shapiro-Wilk test will be run to verify sample normality distribution. The Two-Way ANOVA test will be used for comparative analysis inter and intra-groups. The P value ($p < 0.05$) will be used to establish the significance of the results, in addition to the 95% Confidence Interval (95% CI). The values will be described as a mean \pm standard deviation.

3.7. Ethical Aspects

The present study is grounded on the ethical principles, with base on the Resolution n° 466 of December 12th, 2012, of the National Health Council, which incorporates under the individual and collectivities optics, the four basic references of the bioethics: autonomy, non-maleficence, beneficence, and justice, among others, aiming to ensure the rights and duties which concern the scientific community, the research subjects, and the State.

4. CHRONOGRAM

The present research project will attend the following steps:

1. Bibliography review
2. Writing the project
3. Submission to the Ethics Committee in Research with Humans of the Universidade Federal de Santa Catarina
4. Execution of pilot project
5. Data collection and intervention
6. Data analysis
7. Discussion of the data and results
8. Submission of manuscripts and presentation of the results on national or international events

Etapa	08-11/17	12/17	02-03/18	04/18	05-12/18	01-04/19	05/19
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APPENDICE
INFORMED CONSENT FORM

Dry Needling and Photobiomodulation in the treatment of Myofascial Pain

Participant's Name: _____

Address: _____

Phone: _____

Dear participant, the information presented in this document, **delivered** by the professor Rafael Inácio Barbosa, have the aim to firm the writing agreement by which you authorize your participation in this research with full knowledge of the nature of the procedures and the risks that you will be submitted,

1. RESEARCH PRESENTATION: the present study aims to analyze the effects of dry needling protocols associated with photobiomodulation and to compare it with a placebo protocol. You will be submitted to a pre-intervention evaluation and you will be allocated randomly in one of the three groups where a single intervention will be performed, followed by reassessment soon after the intervention, and two other evaluations one week and one month after the intervention. The groups of participants' allocation are: DN-ON Group, DN-OFF Group, and Control / Placebo Group.
2. DISCOMFORTS AND EXPECTED RISKS: you will be subjected to one of the protocols that may have some risk and discomfort. The intervention with photobiomodulation presents minimal risks and discomforts. Since Dry Needling is a more invasive intervention, it can cause discomforts. The participant may feel discomfort and pain during the technique, however, this should be resolved within a few hours after application. There is a minimal risk of contamination of the needle, which will be controlled through the use of individual and sterilized needles, as well as application site asepsis and the use of glove by the therapist. Finally, the dry needling technique in upper trapezius muscle has the risk of pneumothorax, which will be avoided by performing the correct grip and the control of the needling depth.
3. INFORMATION: you are guaranteed that you will receive the answer to any

question or clarification of any doubt regarding the procedures, risks, benefits and other subjects related to the research by the principal researcher. The results of the research will be made public through publication in reports, articles, presentations at scientific events and / or dissemination of another nature.

4. **WITHDRAW OF THE CONSENT:** you have the freedom to withdraw your consent at any time and stop to participate in the study without penalty.

5. **LEGAL ASPECTS:** the present study is grounded on the ethical principles, with base on the Resolution nº 466 of December 12th, 2012, of the National Health Council, which incorporates under the individual and collectivities optics, the four basic references of the bioethics: autonomy, non-maleficence, beneficence, and justice, among others, aiming to ensure the rights and duties which concern the scientific community, the research subjects, and the State. If you have any doubt, or if you feel the need, you can contact the Ethics Committee in Research with Human of the Universidade Federal de Santa Catarina (UFSC), located at Campus Florianópolis, 222, Desembargador Vitor Lima Street, store 401, Trindade, Florianópolis/SC, by the phone +55 (48) 3721-6094 or through the e-mail cep.propsq@contato.ufsc.br.

6. **PRIVACY GUARANTEE:** the researcher ensures the privacy of the participants as to the confidential data involved in the research.

7. **LOCAL OF THE RESEARCH:** the study will be developed in the Laboratório de Avaliação e Reabilitação do Aparelho Locomotor (LARAL), located at Universidade Federal de Santa Catarina / Campus Araranguá, Rodovia Jorge Lacerda, nº 3201 – km 35,4 – Jardim das Avenidas, Araranguá/SC, Brazil. Zip Code: 88906-072.

8. **BENEFITS:** by participating in this research, you may experience improvement in pain related to trigger points, increase in pressure pain threshold, improvement in pain questionnaire score and neck dysfunction, among other beneficial effects such as muscle relaxation provided by the therapeutic resources used in research. Once the study will compare different intervention protocols, if you are allocated in a group to which the final result shows less effect compared to the others, you can request the intervention that obtained the best result after the end of the study. Moreover, your participation will enable the researcher to obtain important information regarding muscular behavior and

pain related to the use of therapeutic resources in myofascial pain.

9. PAYMENTS: you will have no onus for participating in this research, nor will you pay anything for your participation. If there is any transportation cost, it will be the responsibility of the responsible research. Furthermore, if any extraordinary expenses associated with the research occur, you will be reimbursed under the law.

10. PREJUDICE TO THE PARTICIPANT: if you have material or immaterial damages as a result of the investigation, you may request compensation, guaranteed by the Resolution n° 466 of December 12, 2012, in accordance with current and widely constituted legislation.

11. CONTACT: you can contact the responsible researcher for this study, Rafael Inácio Barbosa, PhD, through the phones +55 (48) 3721-6448 and +55 (48) 99688-7711, or through the e-mail rafael.barbosa@ufsc.br

12. CONSENT POST-INFORMATION

I, _____, CPF/RG _____, after the reading and understanding this Informed Consent Form, understand that my participation is voluntary, and that I can leave the study at any moment, without prejudice. I confirm that I received one copy of this Informed Consent Form, and I authorize the execution of the research and the divulgation of the data obtained in this study in the scientific environment.

DO NOT SIGN THIS FORM IF YOU HAVE ANY DOUBT ABOUT IT

Araranguá, _____, 20____

Participant

ONLY FOR THE STUDY PRINCIPAL INVESTIGATOR

I declare that I have obtained in an appropriate and voluntary manner the Informed Consent of this participant as a condition for participation in this study.

Araranguá, _____, 20____

Rafael Inácio Barbosa, PhD.

Study Principal Investigator.