

## Research Protocol

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# Influence of Phototherapy on Thermographic Images and Pain in Individuals with Temporomandibular Disorder: Protocol for a Randomized, Placebo-Controlled, Double-Blind Clinical Trial

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### ABSTRACT

Considering the multifactor aspect of TMD, studies are needed to establish effective forms of treatment. Thus, the following is the research question of the proposed study: Is phototherapy capable of reducing pain and influencing skin surface temperature over the masseter and temporal muscles in patients with TMD?

**Study Design:** A randomized, placebo-controlled, double-blind study is proposed.

**Sample:** Thirty-six women will participate in the study and will be allocated to two groups (18 per group) through a randomization process involving the use of opaque envelopes containing cards stipulating to which group each participant will belong: Group A (39.27 Joules) and Group B (0 Joules).

**Evaluation Procedures:** Diagnosis of TMD (RDC/TMD), Classification of TMD (FONSECA INDEX), Pain intensity (VISUAL ANALOG SCALE), Pain pressure threshold (ALGOMETRY) and Skin surface temperature (INFRARED THERMOGRAPHY).

**Intervention Procedures:** A portable, nine-diode cluster phototherapy device (PainAway®, MultiRadiance Medical®, Solon, OH, USA) will be used for the administration of phototherapy.

**Phases of Study:** Initial evaluation, Treatment, Immediate evaluation, 10-minute evaluation, 20-minute evaluation and 30-minute evaluation.

**Data Analysis:** Pain, based on the VAS and algometric scores, will be the primary outcome and skin surface temperature will be the secondary outcome.

**KEYWORDS:** Temporomandibular joint disorder; Pain; Laser; Skin Temperature; Thermography.

**ABBREVIATIONS:** TMD: Temporomandibular disorder; LLLT: L-level laser therapy; LED: Light-emitting diode; RDC/TMD: Research Diagnostic Criteria for Temporomandibular Disorders; VAS: Visual Analogue Scale.

### INTRODUCTION

Temporomandibular disorder (TMD) is characterized by a set of clinical conditions involving the masticatory muscles, temporomandibular joint and associated structures. Pain is one of the most common and limiting clinical manifestations of this disorder<sup>1</sup> and can compromise both quality of life<sup>2</sup> and sleep,<sup>3</sup> all of which are related to psychological aspects, such as depressive states, anxiety and stress.

The best clinical approach to patients with TMD involves a multidisciplinary team of

healthcare professionals, including a physiotherapist. A number of studies have addressed the use of physiotherapeutic resources for individuals with this disorder, such as electrotherapy,<sup>4,5</sup> laser therapy<sup>6,7</sup> and manual therapies (massage and joint mobilization).<sup>8,9</sup> Phototherapy has been employed in such cases as a biomodulating agent capable of promoting analgesic and anti-inflammatory effects through the induction of cellular and systemic responses.<sup>6</sup> The effect of phototherapy may be explained by the increase in beta-endorphins, reduction in bradykinin and the release of histamine, increase in lymphatic flow, reductions in swelling and pain-producing substances, increase in blood flow, reduction in the duration of inflammation and the promotion of muscle relaxation.<sup>10,11</sup>

A number of positive effects have been identified with the use of L-level laser therapy (LLLT) in different adverse health conditions due to its capacity to penetrate tissues, thereby influencing the synthesis, release and metabolism of signaling substances involved in analgesia.<sup>12</sup> Hotta, et al.<sup>13</sup> found improvements in patients with TMD following the administration of LLLT, but other authors have not reported satisfactory results.<sup>10,11</sup> The studies cited were performed with different age groups and did not employ standardized protocols regarding the variables analyzed. A Light-emitting diode (LED) is a semiconducting diode (P-N junction) that emits light when energized. LED therapy has recently been employed as an alternative to LLLT, demonstrating similar results with the added advantages of the lower cost and durability of the device.<sup>14</sup>

It is important to evaluate the effect of phototherapy on the masticatory muscles. For such, infrared thermography has been employed for the study of skin surface temperature,<sup>15</sup> which is an indirect measure of changes in blood circulation. According to Johansson, et al.<sup>16</sup> skin temperature can be influenced by circulatory changes in deep tissues, such as muscles, tendons, ligaments and synovial membranes. Thermography allows mapping the body or a segment of the body to distinguish areas with different temperatures. This method allows the visualization of light in the infrared spectrum.

Dibai Filho, et al.<sup>17</sup> evaluated the use of infrared thermography over the masticatory muscles (masseter and anterior temporal muscles, bilaterally) in individuals with myogenous TMD, diagnosed using the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD), and found that the method is not accurate for the diagnosis of this disorder. However, Costa, et al.<sup>18</sup> evaluated the reliability of two forms of infrared image analysis of the masticatory muscles and upper trapezius muscle in women with and without TMD and found that both forms of analysis demonstrated excellent intra-examiner and inter-examiner reliability. The authors proposed both evaluation methods for these muscles, especially when the goal is to evaluate the effect of therapeutic resources. The divergences in the findings of the studies cited underscore the need for further investigations with well-defined methods.

Considering the multifactor aspect of TMD,<sup>19</sup> studies are needed to establish effective forms of treatment. Thus, the following is the research question of the proposed study: Is phototherapy capable of reducing pain and influencing skin surface temperature over the masseter and temporal muscles in patients with TMD?

## OBJECTIVES

The primary objective is to propose a protocol that allows:

- Evaluating the effect of phototherapy on pain and skin surface temperature over the masseter and temporal muscles in individuals with TMD;
- Evaluating the relationship between a change in skin surface temperature and pain.

## METHODS

### Ethical Aspects

This study received approval from the Institutional Review Board of University Nove de Julho (São Paulo, Brazil) on June 12, 2013 under process number 18032013.4.0000.5511.

### Study Design

A randomized, placebo-controlled, double-blind study is proposed, in which one researcher will be in charge of administering the treatment protocols, another will perform the evaluations and a third researcher will be responsible for the statistical analysis of the data.

Primary outcome: Pain

Secondary outcome: Skin surface temperature

### Sample

Thirty-six women will participate in the study and will be allocated to two groups (18 per group) through a randomization process involving the use of opaque envelopes containing cards stipulating to which group each participant will belong: Group A (39.27 Joules) and Group B (0 Joules).

The sample size was calculated considering  $\alpha=0.05$  (5% chance of a type I error) and  $1-\beta=0.95$  (% of power of the sample) based on data using the Visual Analogue Scale (VAS) described in a study conducted by Pereira et al<sup>20</sup>:  $6.91\pm 1.6$  pre-laser treatment and  $4.65\pm 2.5$  24 hours after laser treatment. Fifteen individuals were estimated for each group, to which 20% were added to compensate for possible dropouts (18 individuals per group). The sample size calculation was performed using the G\*Power program (Faul et al).<sup>21</sup>

The study will involve women aged 18 to 40 years with a diagnosis of TMD confirmed by the RDC/TMD. The participants will be recruited from the physical therapy and dentistry clinics of University Nove de Julho, São Paulo, Brazil. The choice of gender and age group was based on the greater prevalence rates of TMD in these groups of patients.<sup>22</sup>

#### Inclusion Criteria

All volunteers must have a diagnosis of myogenous TMD, with moderate to severe pain in the masticatory muscles based on the RDC/TMD. The volunteers must also have a pain score in the masticatory muscles greater than 3 points on the VAS.<sup>23</sup>

#### Exclusion Criteria

To standardize the sample, women with missing teeth, the use of complete or partial dentures, systemic diseases, neuromuscular problems, a history of trauma to the face or temporomandibular joint, a history of luxation of the temporomandibular joint, those with a diagnosis of IIIb (osteoarthritis) or IIIc (osteoarthrosis) on the RDC/TMD, those in orthodontic treatment and those using medications that affect the musculoskeletal system (analgesic, anti-inflammatory agent, muscle relaxant or vasoactive drug) will be excluded from the study.

#### Randomization and Blinding

The participants will be allocated to the two groups in a randomized and stratified fashion using sealed, opaque envelopes: Group A (39.27 Joules) and Group B (0 Joules). The participants will be blinded to the allocation of the different groups. The phototherapy device that will be used will emit sounds independently of the programmed dose. One researcher will be in charge of the randomization and stratification of the groups and will program the phototherapy device based on the results of the randomization process. A second researcher will perform the phototherapy and will be blinded to the dose being administered. A third researcher will be in charge of the evaluations and will also be blinded to the allocation of the patients to the different groups. The statistician will be blinded to the allocation until concluding the statistical analyses.

#### EVALUATION PROCEDURES

##### Diagnosis of TMD (RDC/TMD)

The RDC/TMD will be used for the diagnosis of TMD.<sup>24</sup> This system allows the classification of individuals with TMD into the following groups: I) muscle disorder; II) disc displacement; and III) other joint conditions. An individual can pertain to one, two or all three groups simultaneously.

As pain is the primary outcome, all volunteers must have myofascial pain. Therefore, the RDC/TMD will be used to

determine whether the individuals meet the inclusion criteria.

The RDC/TMD has two axes. Axis I consists of a clinical exam, which will be performed by an examiner who has undergone training and calibration exercises based on the specifications of the International RDC/TMD Consortium. This exam is used to evaluate muscle and joint pain, mouth opening pattern, mandibular range of motion, joint sounds and pain sensitivity during mandibular movements or muscle and joint palpation. The duration of the exam is roughly 20 minutes. For this, the volunteer will remain seated in a chair with the trunk erect and back supported, feet planted on the floor and hands resting on the thighs, with the Frankfurt parallel to the floor. The examiner will be positioned in front of the volunteer.

Axis II classifies an individual based on the degree of chronic pain, depression and non-specific physical symptoms. This axis will be administered after the clinical exam. The volunteer will be instructed to answer the questionnaire with no time constraints.

##### Classification of TMD (FONSECA INDEX)

The Fonseca Patient-History Index<sup>25</sup> has been used by a number of authors for the classification of the severity of TMD symptoms.<sup>26,27</sup> This index has 10 questions that are easy to apply and understand. Each question has three response options (yes, no and sometimes), which are respectively scored as 10, 0 and 5 points. Only one response is allowed for each question. The total score results from the sum of all questions and is used to classify the severity of signs and symptoms of TMD: 0 to 15 points=absence of TMD; 20 to 40 points=mild TMD; 45 to 60 points=moderate TMD; and 70 to 100 points=severe TMD.

##### Pain Intensity (VISUAL ANALOG SCALE)

The VAS is used to measure pain intensity and consists of a 10-cm straight line. The term “no pain” is written at one extremity (0 cm) and the term “worst pain ever felt” is written at the other extremity (10 cm). The volunteer will be instructed to mark a perpendicular line between to the extremes that best represents the pain intensity she is feeling at the moment.<sup>28</sup>

##### Pain Pressure Threshold (ALGOMETRY)

A digital algometer (DD-200 model, Instrutherm®) will be used to determine the pressure pain threshold. For this, the volunteer will remain seated in a chair with the trunk erect and back supported, feet planted on the floor and hands resting on the thighs, with the Frankfurt parallel to the floor. The examiner will position the algometer and exert gradual pressure over the masseter and anterior temporal muscles, bilaterally, following the guidelines of Axis I of the RDC/TMD. All points will received pressure until the volunteer reports the sensation of pain, at which time the value on the display of the equipment will be recorded. If the volunteer does not experience pain, pressure will

be ceased upon reaching 4 Kgf.<sup>29</sup>

### Skin Surface Temperature (INFRARED THERMOGRAPHY)

The volunteers will be instructed to avoid hot baths or showers, the use of topical agents, creams or talcum, the practice of vigorous exercise and the ingestion of stimulating substances, such as caffeine, nicotine or chocolate, for at least two hours before the exam.<sup>15</sup> Prior to the exam, the volunteer will remain in a temperature-controlled environment (22 °C) for 20 minutes without the presence of heat-generating equipment or the entrance of air or sunlight. The exam room will be lit with fluorescent bulbs. During the data collection, the volunteer will remain seated on a stool with the trunk erect, hands resting on thighs and gazing forward. The region of the muscles being evaluated will be free of clothing and personal objects (earrings, necklaces or other accessories) and the hair will be pinned back, if necessary.<sup>30</sup>

A thermal camera (T450 SC model, FLIR® Systems, Stockholm, Sweden) will be used with emissivity established at 0.98 and the instrument will be stabilized for 10 minutes prior to the exam. The image will be captured at a distance of 100 cm from the volunteer to allow the framing of the muscles being evaluated.<sup>31</sup> Polystyrene markers will be used. For the anterior temporal muscle, one marker will be positioned on the frontal bone immediately above the belly of the muscle and another marker will be positioned near the lateral corner of the eye. For the masseter muscle, one marker will be positioned on the zygomatic arch and another will be positioned on the lateral face of the angle of the mandible.

The temperature measurements on the infrared images will be performed by a single examiner who will be blinded to the allocation of the patients to the different groups. For this, the Quick Report program, version 1.1 (FLIR® Systems, Stockholm, Sweden) will be employed. The use of absolute temperatures for the diagnosis or the evaluation of the effects of therapy is insufficient, as inter-individual variations are not taken into account. To correct for such errors, Vargas, et al.<sup>32</sup> propose the use of normalized temperature values by employing the following equation:  $\theta = \frac{T - T_{\infty}}{T_b - T_{\infty}}$ , in which T is the skin surface temperature in °C,  $T_b$  is the central temperature in °C and  $T_{\infty}$  is the room temperature in °C.

### Intervention Procedures

A portable, nine-diode cluster phototherapy device (PainAway®, MultiRadiance Medical®, Solon, OH, USA) will be used for the administration of phototherapy. This device has one LLLT diode at 905 nm, four LED diodes at 875 nm and four LED diodes at 670 nm. The device has a beam spot of 4 cm<sup>2</sup>. Table 1 displays the parameters of the PainAway® device. The decision to use this equipment was based on its high quality and the fact that no Brazilian firms manufacture cluster phototherapy devices, especially with the characteristics necessary for the ex-

ecution of the proposed study.

For the blinding of the participants, the equipment with different light sources has two identical application pens furnished by the manufacturer: one with an active tip and one with a placebo tip that does not emit energy. Both pens have identical sound devices. The tips will be denominated X and Y by a researcher who will not participate in either the treatment or evaluations. The patients and researchers in charge of the administration of the phototherapy and the evaluations will be unaware of which pen emits the active dose and which is the placebo device. The pens will be identified only at the end of the data collection procedures. Table 1 displays the doses and application times per point in each group.

|   |                         |
|---|-------------------------|
|   | PainAway®               |
| Number of lasers                          | 1 Super pulsed infrared |
| Wavelength of laser (nm)                  | 905                     |
| Frequency (Hz)                            | 1000                    |
| Mean optical output (mW)                  | 0.9                     |
| Peak power (W)                            | 8.5                     |
| Total dose (J) per group (300s)           | 0.27                    |
| Beam spot size (cm <sup>2</sup> )         | 0.4                     |
|   |                         |
| Number of LEDs                            | 4 red                   |
| Wavelength of LED (nm)                    | 640                     |
| Frequency (Hz)                            | 2                       |
| Mean optical output (mW)                  | 15                      |
| Dose (J) of each emitter per group (300s) | 4.5                     |
| Total dose (J) per group (300s)           | 18                      |
| Beam spot size (cm <sup>2</sup> )         | 0.9                     |
|   |                         |
| Number of LEDs                            | 4 Infrared              |
| Wavelength of LED (nm)                    | 875                     |
| Frequency (Hz)                            | 16                      |
| Mean optical output (mW)                  | 17.5                    |
| Dose (J) of each emitter per group (300s) | 5.25                    |
| Total dose (J) per group (300s)           | 21                      |
| Beam spot size (cm <sup>2</sup> )         | 0.9                     |
|   |                         |
| Magnetic field (mT)                       | 35                      |
|   |                         |
| Duration of treatment (s)                 | 300s (5min)             |
|   |                         |
| Aperture of device (cm <sup>2</sup> )     | 4                       |
|   |                         |
| Total energy delivered (J)                | 39.27                   |
|   |                         |
| Total energy delivered (J) per treatment  | 392.70                  |

Table 1: Phototherapy parameters.

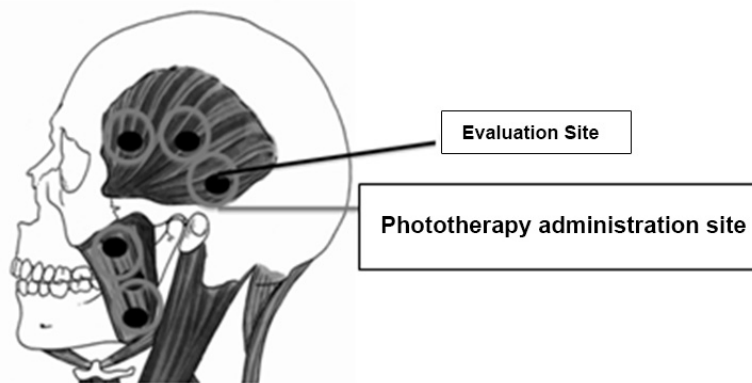


Figure 1: Illustration of phototherapy irradiation sites.

### Phases of Study

The study will be divided into six phases:

**Initial evaluation:** Individuals who meet the eligibility criteria will be submitted to the RDC/TMD, Fonseca Index, VAS, algometry and thermography;

**Treatment:** Following randomization and stratification, phototherapy will be administered based on the parameters established for the different groups (active therapy or placebo);

**Immediate evaluation:** After treatment, the initial evaluation will be repeated, except for the RDC/TMD;

**10-minute evaluation:** 10 minutes after the treatment protocol, the initial evaluation will be repeated, except for the RDC/TMD;

**20-minute evaluation:** 20 minutes after the treatment protocol, the initial evaluation will be repeated, except for the RDC/TMD;

**30-minute evaluation:** 30 minutes after the treatment protocol, the initial evaluation will be repeated, except for the RDC/TMD.

### Data Analysis

Pain, based on the VAS and algometric scores, will be the primary outcome and skin surface temperature will be the secondary outcome. The different light sources used for phototherapy will be the independent variables. The dependent variables will be derived from the pre-treatment and post-treatment evaluations. The Shapiro-Wilk test will be used to test the data with regard to Gaussian distribution. Data with normal distribution will be expressed as mean and standard deviation values. Data with non-normal distribution will be log-transformed. Two-way (group and treatment) repeated-measurements analysis of variance and the Bonferroni post hoc test will be used for the inter-group and intra-group comparisons. The SPSS program, version 13.0 (Chicago, IL, USA) will be used for the statistical analyses, with the level of significant set to 5% ( $p < 0.05$ ) for all comparisons.

### Description of Work Plan

The project is predicted to last 24 months and will be divided into the following steps: A-Drafting of project and submission to Institutional Review Board; B-Purchasing of equipment; C-Pilot study; D-Planning and determination of sample size; E-Submission of project to Clinical Trials Registry; F-Selection of participants; G-Data collection and application of protocols; H-Data analysis; I-Description of Results, Discussion and Conclusion; J-Drafting and submission of scientific article.

### DISCUSSION

Pain is the main symptom of TMD, with muscle and/or joint involvement the most prevalent manifestations in the population. Other signs and symptoms include limited range of motion of the mandible, joint sounds, ontological manifestations, lack of motor coordination and muscle sensitivity.<sup>33</sup>

Considering pain as the main symptom of TMD, clinicians are constantly searching for resources that enable the immediate relief of this discomfort. LLLT has been gaining ground in the offices of physicians, dentists and physiotherapists as well as in clinical trials, as studies have demonstrated its benefits in terms of anti-inflammatory action, analgesia and as an inducer of cell proliferation.<sup>34</sup> Thus, LLLT has been employed as a physical means in the treatment of TMD due to its therapeutic effects.<sup>11</sup> However, despite its use in the treatment of different adverse health conditions,<sup>34</sup> the effects depend on the dosimetric parameters and systemic conditions of the patient<sup>35</sup> and there is no consensus in the literature regarding the definition of the best wavelength and exposure time. Using algometry and thermography as the evaluation parameters, Hakguder, et al.<sup>36</sup> concluded that LLLT is beneficial to patients with myofascial pain.

Considering the complex diagnosis and lack of a gold standard, the evaluation of individuals with TMD should be directed toward the specificities of the disorder, involving joint evaluations that address the multiple structures affected.<sup>37</sup> In this context, the RDC/TMD and Fonseca Index have been employed as assessment methods for the diagnosis and degree of sever-

ity of TMD, respectively.<sup>24,25,38</sup> The RDC/TMD is currently considered the most complete assessment tool for the evaluation of individuals with TMD, as it encompasses the physical and psychological aspects related to this disorder and allows different diagnoses based on the involvement of the masticatory muscles, joint disc and/or temporomandibular joint.<sup>24,39</sup>

For the specific evaluation of pain, algometry is considered the standard of reference in the literature.<sup>40,41</sup> Visscher, et al.<sup>42</sup> concluded that the use of algometry in the identification of pain complaints in TMD is comparable to manual palpation. In the proposed study, the decision was made to evaluate pain through both algometry and manual palpation (recommended in the RDC/TMD) for greater reliability in the results.

Recently, thermography has been employed to evaluate patients and monitor the therapeutic effects of different treatments. This method has been used in different fields, such as the military, engineering and astronomy, due to its capacity to detect long waves of the infrared spectrum. The use of thermography in medicine began in the 1960s. However, with technological advancements, this method has recently acquired characteristics that are compatible with the needs of the health sciences.<sup>15</sup> The advancement in the field of medicine is due to the fact that the thermal image allows the detection of changes in blood circulation that can occur as a result of inflammatory processes, angiogenesis and other causes. Thus, thermography has become an important indicator of abnormalities, since the asymmetrical distribution of temperature, with the presence of cold and hot areas, is strongly suggestive of disorders.<sup>43</sup> Infrared thermography has been described in the literature as an assessment tool for individuals with different adverse health conditions, such as carpal tunnel syndrome,<sup>44</sup> breast cancer,<sup>45</sup> circulatory changes,<sup>46</sup> myofascial disorders<sup>31</sup> and TMD.<sup>17,18</sup> This painless, noninvasive, non-ionizing method does not require contact with the region being evaluated, thereby offering safety and comfort to the patient.<sup>15</sup>

A number of studies have been conducted, but there is still no consensus. Some studies suggest that a temperature difference greater than 0.5 °C is indicative of a pain disorder.<sup>47</sup> According to Dibenedetto, et al.<sup>48</sup> A change greater than 1 °C is invariably indicative of an abnormality, based on a survey involving 1000 soldiers. According to Brioschi, et al.<sup>49</sup> an asymmetrical pattern equal to or greater than 0.3 °C suggests an abnormality of the sympathetic system stemming from a traumatic injury, inflammation or local vascular changes. In contrast, Hadad & Saito<sup>50</sup> wrote a dissertation describing their thermographic analysis, in which myofascial trigger points in the masseter and temporal muscles were found to be hyporadiant. The authors raise the hypothesis that this is due to a sarcometric contraction of the muscle fibers, a reduction in blood flow and consequent local hypoxia.<sup>41,51</sup> The authors also suggest that their findings confirm the usefulness of thermography in the evaluation of pain in the masticatory muscles, especially when used as a physical examination in conjunction with complementary exams.

As phototherapy promotes changes in the blood flow in the region to which it is administered, the benefits of thermography regarding the evaluation of this physiotherapeutic modality seem clear. Moreover, phototherapy is capable of promoting muscle relaxation,<sup>11</sup> which demonstrates the need to monitor the muscle pattern through surface electromyography, which is a widely employed assessment tool in studies addressing TMD.

#### FINAL CONSIDERATIONS

With the advancements in clinical trials, clinicians have constantly sought out evidence-based therapies. For this, well-defined methods should be tested for their diagnostic efficacy as well as the evaluation of the effects of proposed treatments. Thus, this protocol study aims to combine evaluation methods to monitor the use of phototherapy for the treatment of individuals with TMD and broaden knowledge regarding its therapeutic effects.

#### CONFLICTS OF INTEREST

The authors declare that they have no conflicts of interest.

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