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ORIGINAL ARTICLE

# Simultaneous red and infrared light-emitting diodes reduced pain in individuals with temporomandibular disorder: a randomized, controlled, double-blind, clinical trial

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## Abstract

The aim of the present study was to evaluate the effects of photobiomodulation (PBM) with the simultaneous use of red and infrared LEDs on pain and mandibular range of motion in individuals with temporomandibular disorder (TMD). Eighteen participants were randomly allocated to an LED group or control group. The device had 18 red LEDs (660 nm) and 18 infrared LEDs (850 nm), with a total power irradiated of 126 mW and 75.6 J per point. The device was placed in the regions of the temporomandibular joint (TMJ) and masticatory muscles once per day three times per week for 2 weeks. Pain intensity was measured using the visual analog scale (VAS). Mandibular range of motion was determined using digital calipers and considering different conditions (unassisted opening without pain, maximum opening with and without assistance, right and left lateral movements, and protrusion). Evaluations were performed before treatment, immediately after the first LED irradiation session and at the end of six sessions. A significant reduction in pain intensity was found in the LED group at the end of treatment compared to the control group ($p < 0.001$) as well as in the comparison between the pretreatment and end of treatment evaluations ($p < 0.001$). Regarding mandibular movements, no statistically significant differences between the LED group and control group were found at the end of treatment for any of the conditions analyzed or in the comparison between the beginning and end of treatment with LED. Photobiomodulation using a cluster with red and infrared LEDs induced a reduction in pain in individuals with temporomandibular disorder but did not alter mandibular range of motion in these individuals. Trial registration number: NCT03696706; retrospectively registered (ClinicalTrials.gov).

**Keywords** Photobiomodulation · LED · Temporomandibular disorder · Pain · Mandibular range of motion

## Introduction

Temporomandibular disorder (TMD) is a generic term for clinical signs and symptoms that affect the temporomandibular joint (TMJ), masticatory muscles, and associated structures [1–3]. Due to the complexity of this condition, Freire et al. (2014) [4] suggest multidisciplinary treatment. Different non-surgical approaches have been used for the treatment of TMD, such as pharmacological resources [5, 6], the use of a rigid occlusal splint for myorelaxation [7], physiotherapeutic treatments, such as electrotherapy [8], massage therapy, and joint mobilizations [9, 10], and the use of therapeutic light (photobiomodulation) [11–15].

Photobiomodulation (PBM) is non-ionizing radiation that promotes the interaction of light and biological tissues, enabling photophysical effects with photochemical and photobiological responses [11]. PBM in the form of low-level laser therapy (LLLT) stimulates blood flow, promotes an anti-inflammatory response [16], and influences the synthesis, release, and metabolism of numerous signaling molecules involved in analgesia [17–19]. Other advantages of treatment with PBM included its ease of administration, noninvasive nature with minimal

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contraindications, and the possibility of shorter, low-cost treatments, making it a treatment option for individuals with TMD [1, 3, 20–23].

Light-emitting diodes (LEDs) constitute an attractive form of therapeutic PBM, with an increasing number of clinical trials demonstrating positive effects in cases of TMD [14, 15, 24]. PBM with LED achieves similar results as those found with the use of LLLT and offers the advantages of a more affordable device [25] and possibility of customization with clusters of multiple LEDs, enabling the irradiation of a larger area [24].

Studies suggest that red or infrared LED therapy increases muscle activity after the induction of masseter muscle fatigue [26], promotes pain relief of the masseter muscle [15, 27], and reduces the inflammatory process of the TMJ [28] in individuals with TMD. Furthermore, comparative studies in the literature report similar effects of red and infrared LED administered to the TMJ and masticatory muscles regarding pain relief and improvements in mandibular range of motion [29].

Herpich et al. (2017) [14] showed that the combination of different wavelengths is beneficial for individuals with TMD. The energy absorption rate and penetration into biological tissues differ between red and infrared spectra, enabling distinct cellular responses to this form of stimulus [14, 30]. However, no previous studies have investigated the simultaneous use of multiple red and infrared LEDs in the same device for the treatment of TMD.

Therefore, the aim of the present study was to analyze the effects of photobiomodulation with simultaneous use of red LEDs (660 nm) and infrared LEDs (850 nm) in the same device on pain intensity and mandibular range of motion in individuals with TMD.

## Materials and methods

### Design

A randomized, controlled, double-blind, clinical trial was conducted at the dental clinic of Universidade Nove de Julho (UNINOVE) in the city of São Paulo, Brazil. The methods were previously specified in a published protocol study [31]. This study received approval from the local human research ethics committee (process number: 2.962.857). All potential participants received clarifications regarding the objectives and procedures and those who agreed to participate voluntarily signed a statement of informed consent, as stipulated in Resolutions 466/2012 and 510/2016 of the Brazilian National Board of Health. This study was registered with Clinicaltrials.gov (NCT 03,696,706).

### Sample size calculation

The sample size was calculated considering $\alpha = 0.05$, $1 - \beta = 0.9$, and data described in the study by Herpich et al. (2017) [14]. The sample was determined to be 11 participants in each group (experimental and control). Suresh and Chandrashekara (2012) [32] suggest a minimum sample of eight participants per group to enable adequate statistical analyses in clinical studies with difficulty recruiting volunteers.

### Participants

The clinical diagnosis of mixed TMD using the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) [33] was used to diagnose the participants. This evaluation tool, which has been validated in its Portuguese language version [34], has two axes for a detailed physical evaluation of the mouth opening pattern, vertical extension of mandibular movement, lateral excursions, and protrusion as well as an evaluation of TMJ noises upon palpation. The questionnaire is composed of items addressing general health, oral health, a history of facial pain, limited mouth opening, joint noises, habits, bite, tinnitus, general diseases, joint problems, headache, current behavior, and socioeconomic profile. The participants should have a complete dentition (except third molars) and present mandibular deviation and/or deflection.

The exclusion criteria were occlusal alterations, any type of dental prosthesis, currently undergoing orthodontic or physiotherapeutic treatment, and starting the use of medication during any of the phases of the study.

Eligible volunteers were instructed to remain without any physiotherapeutic and/or dental interventions and not to use any medications for 2 weeks. This period was considered the control phase. Randomization was performed via www.randomization.com, using 1:1 block randomization with permutation and changing block sizes. The participants were then sent to the interventions according to allocation to the different groups: LED group (active PBM in six non-consecutive sessions) and the control group (sham PBM with the device "off" mode in six non-consecutive sessions). Evaluations were performed before and after the first session as well as at the end of the treatment.

The procedures were performed by three different researchers (dentists having undergone training exercises for data collection and evaluations). Each researcher was exclusively in charge of one part of the study. The first researcher was responsible for screening the participants and administering the questionnaires. The second was responsible for the randomization process, allocation

concealment (other researchers were blinded to the treatment of each volunteer), and the administration of PBM (active or placebo). The third researcher was responsible for data analysis and processing.

## Photobiomodulation—red and infrared LED treatment

Photobiomodulation was performed following the protocol described by Sousa et al. (2019) [31]. Treatment was administered using the Sportllux device (Cosmedical®, Mauá, SP, Brazil), which is a plate containing a total of 36 LEDs (Fig. 1a) that was attached with an elastic strap to the hemiface of the participant covering the regions of the temporomandibular joints, masseter muscles, and anterior bundle of the temporal muscles (Fig. 1b). The treatment was performed three times per week on non-consecutive days for 2 weeks, totaling six treatment sessions. For placebo treatment (control group), all the procedures described for the LED group were adopted, but with the equipment switched off. Only the volunteer to be treated and the operator were present during treatment, both of whom wore protective eyewear. The LED device was composed of a flexible rectangular plate (120 $cm^2$) that adapts to the shape of the area to be treated, containing 18 red LEDs (660 nm) and 18 infrared LEDs (850 nm). The dosimetric parameters for LED irradiation are shown in Table 1.

A total of 78 participants were screened for the present study. Sixty were excluded for the reasons listed in the flowchart (Fig. 2), which was designed following the Consolidated Standards for Reporting Trials (CONSORT statement) [35]. A total of 18 patients were divided into two groups (nine patients for each group) and were assessed before the first intervention, immediately after the first therapeutic intervention, and at the end of treatment.

## Measures

### Pain intensity

The visual analog scale (VAS) was used to measure pain intensity. This scale consists of a 10-cm line with 0 (no pain) printed at one end and 10 (worst pain ever experienced) printed at the other end. The participants were instructed to mark a perpendicular line between the two ends to represent their current pain intensity. This mark was subsequently measured, recording the distance from zero to obtain a numerical representation of pain intensity [36].

### Range of motion

The extent of vertical mandibular movement (mouth opening), right and left excursions, and protrusion were measured (in millimeters) with the aid of digital calipers (Starrett®, Athol, MA), considering the distance between the maxillary and mandibular central incisors [13, 14]. For the extent of vertical movement, three situations were considered: (1) opening without assistance and without pain, (2) maximum opening without assistance, and (3) maximum opening with assistance. For right and left excursions, the participant was instructed to move the mandible to the right and left sides and the distances between the midlines of the upper and lower dental arches were measured. Lastly, the participant was instructed to perform a protrusive movement.

## Statistical analysis

The data were analyzed using GraphPad Prism 8.0.1. The Kolmogorov–Smirnov test was used to assess normality. Parametric data were expressed as mean ± standard deviation. Nonparametric data were expressed as median and interquartile range. Comparisons between groups were

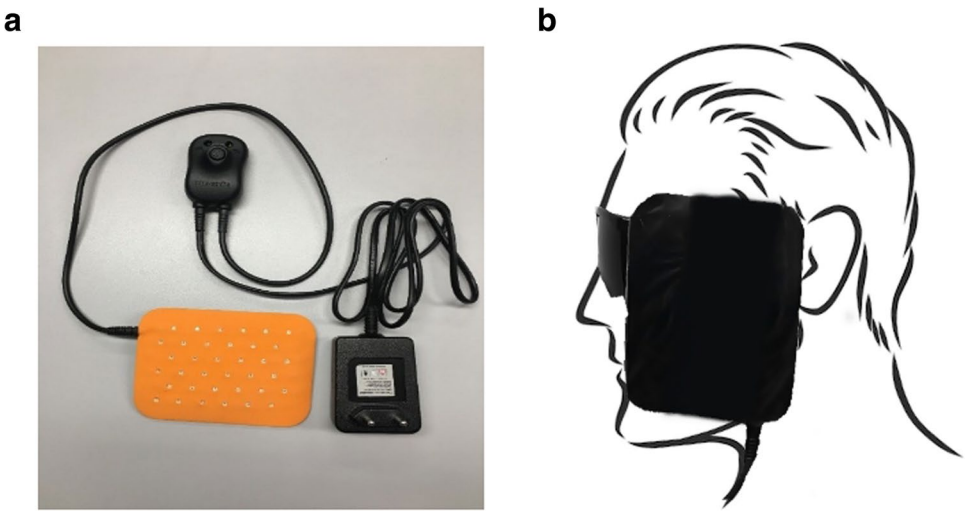


**Fig. 1** Sportllux device (Cosmedical®, Mauá, SP, Brazil) (**a**) and representation of LED plate position for photobiomodulation treatment (**b**)

**Table 1** Dosimetric parameters for red and infrared LED treatment

| | Infrared LED | Red LED |
|---|---|---|
| Wavelength (nm) | 850 | 660 |
| Spectral bandwidth (FWHM) (nm) | 20 | 20 |
| Operating mode | Continuous | Continuous |
| Power (mW)—each | 3.5 | 3.5 |
| Number of LEDs | 18 | 18 |
| Total power irradiated (mW) | 63 | 63 |
| Polarization | Random | Random |
| Aperture diameter (mm)—each | 10 | 10 |
| Irradiance at aperture (mW/cm$^2$) | 4.45 | 4.45 |
| Profile beam | Multimode | Multimode |
| Beam area (cm$^2$)—each | 0.7854 | 0.7854 |
| Irradiance (mW/cm$^2$) | 4.45 | 4.45 |
| Exposure time (s) | 1200 | 1200 |
| Radiant exposure (J/cm$^2$) | 5.35 | 5.35 |
| Energy (J) | 75.6 | 75.6 |
| Number of points irradiated | 18 | 18 |
| Irradiated area (cm$^2$) | 14.13 | 14.13 |
| Application technique | Contact | Contact |
| Number and application frequency | 6 sessions (3 times/week) | 6 sessions (3 times/week) |
| Total energy (J) | 453.6 | 453.6 |

performed using the *t*-test with Welch's correction for parametric data, whereas the Mann–Whitney test was used for nonparametric data. Intragroup comparisons were performed using two-way analysis of variance (ANOVA) for parametric data and the Friedman test with Dunn's post hoc test for nonparametric data. The significance level was set at 5% ($p < 0.05$) for all statistical tests.

## Results

Among the 78 individuals recruited, exclusions occurred due to refusals to participate, failure to meet the eligibility criteria, and not agreeing to perform a facial shave. The final sample was composed of 18 women between 18 and 45 years of age with mixed TMD (myogenic and joint). The mean age was 23.66 (± 3.90) in the LED group and 23.55 (± 3.67) years in the control group. Sample losses occurred during the interventions and subsequent evaluations due to the use of analgesic medication (one participant) and dropouts (eight participants), as shown in Fig. 2. Each group had nine participants. Recruitment and follow-up of participants were conducted between January 2019 and December 2019.

Regarding the clinical diagnosis of TMD using the RDC/TMD, eight participants in the LED group (88.8%) were diagnosed with myofascial pain and one (11.1%) had myofascial pain with limited mouth opening. In the control group, seven participants (77.7%) were diagnosed with myofascial pain and two (22.2%) had myofascial pain with limited opening. In the overall sample ($n = 18$), only three participants (16.6%) had limited mouth opening and all participants (100%) had anterior disk displacement with reduction on the right and/or left side as well as right and/or left arthralgia.

### Pain intensity

Significant differences between groups and evaluation periods were found regarding pain intensity measured using the VAS (Fig. 3). Pain intensity was significantly lower in the LED group compared to the control group at the end of treatment ($p < 0.001$). In the intra-group analysis, a significant reduction was found in the LED group between the preintervention and post-intervention evaluation ($p < 0.001$) as well as between the evaluation immediately after the first session and the post-intervention evaluation ($p < 0.001$).

### Range of motion

The results of the mandibular range of motion analysis are displayed in Table 2. No statistically significant differences between the LED group and control group were found at the preintervention evaluation, evaluation immediately after the first session, or the post-intervention evaluation for any

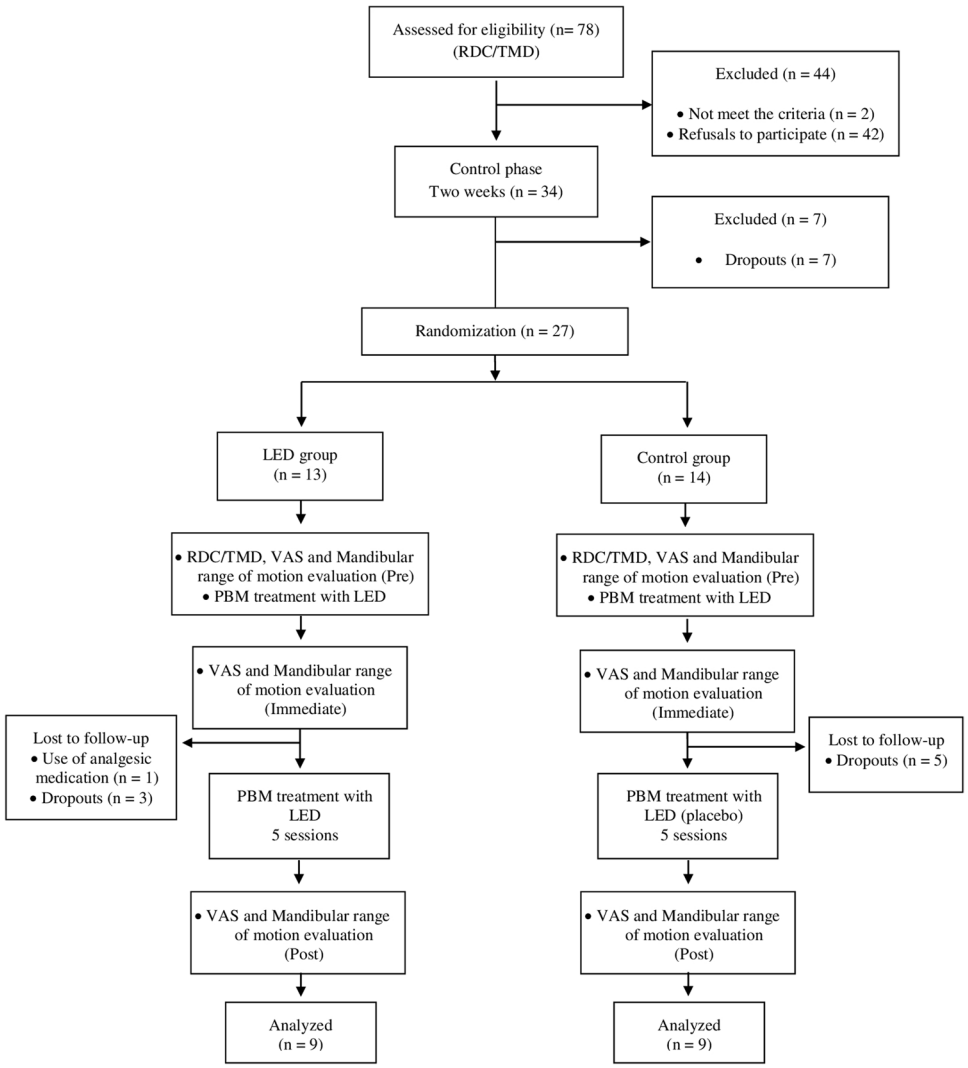


**Fig. 2** Flowchart of the study

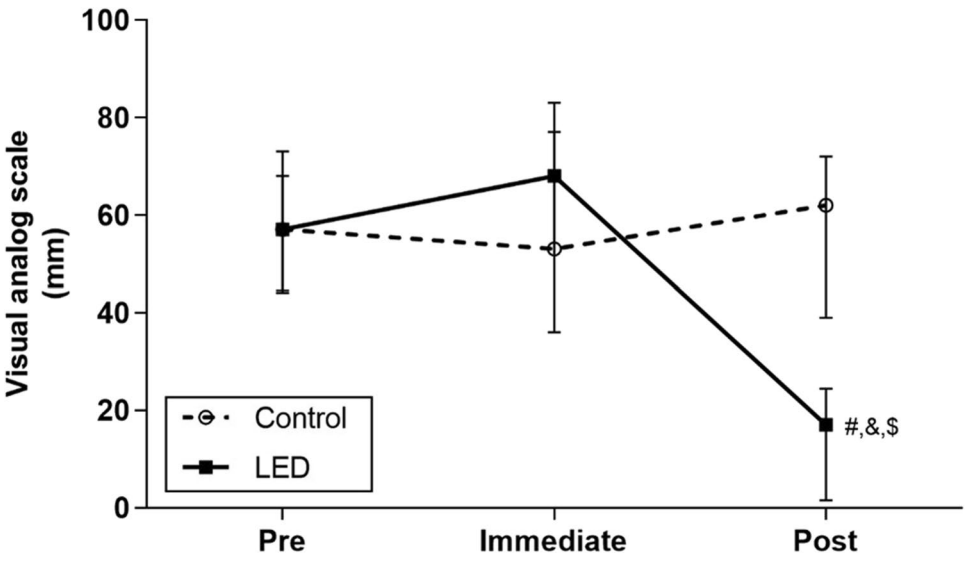


**Fig. 3** Median and interquartile range [25–75%] of pain intensity using visual analog scale in the LED group and control group at different evaluation times. The Mann–Whitney test for inter-group analysis and Friedman test with Dunn's post hoc test for intragroup analysis. Pre, pre-intervention evaluation; Immediate, evaluation after first session; Post, post-intervention evaluation (after six sessions). #Post LED × Post Control; &Post LED × Pre LED; $Post LED × Immediate LED

**Table 2** Mean ± standard deviation (mm) of mandibular range of motion (opening without assistance and without pain; maximum opening without and with assistance; right and left lateral excursions; and protrusion) in LED and control groups at different evaluation times

| *Range of motion* | Pre (T1) | Immediate (T2) | Post (T3) |
|---|---|---|---|
| *Opening without assistance and without pain* | | | |
| LED | 41.9 ± 1.97 | 40.1 ± 2.21 | 42.5 ± 1.92 |
| *Control* | 40.4 ± 1.92 | 38.7 ± 2.28 | 42.4 ± 1.48 |
| *p*-value[a] | *0.60* | *0.67* | *0.98* |
| *Maximum opening without assistance* | | | |
| *LED* | 44.0 ± 1.97 | 41.5 ± 1.85 | 44.2 ± 2.08 |
| *Control* | 42.8 ± 1.74 | 41.5 ± 1.70 | 44.4 ± 1.43 |
| *p*-value[a] | *0.65* | *> 0.99* | *0.94* |
| *Maximum opening with assistance* | | | |
| *LED* | 49.4 ± 1.56 | 47.9 ± 2.08[b] | 48.2 ± 2.20 |
| *Control* | 45.8 ± 1.89 | 42.3 ± 2.27 | 47.3 ± 1.59 |
| *p*-value[a] | *0.16* | *0.09* | *0.76* |
| *Right lateral excursion* | | | |
| *LED* | 7.12 ± 0.750 | 6.97 ± 0.695 | 8.21 ± 0.810 |
| *Control* | 8.81 ± 0.491 | 8.41 ± 0.429 | 8.79 ± 0.433 |
| *p*-value[a] | *0.08* | *0.10* | *0.54* |
| *Left lateral excursion* | | | |
| *LED* | 7.69 ± 0.753 | 7.88 ± 0.687 | 9.07 ± 0.675 |
| *Control* | 8.78 ± 0.481 | 8.51 ± 0.437 | 9.27 ± 0.333 |
| *p*-value[a] | *0.24* | *0.45* | *0.78* |
| *Protrusion* | | | |
| *LED* | 4.14 ± 0.475 | 4.12 ± 0.493 | 5.34 ± 0.493[b] |
| *Control* | 4.92 ± 0.44 | 4.50 ± 0.416 | 5.04 ± 0.451 |
| *p*-value[a] | *0.25* | *0.57* | *0.66* |

[a]*t*-test with Welch correction

[b]Two-way ANOVA, Bonferroni vs. Pre (T1)

of the conditions analyzed ($p > 0.05$). Moreover, no significant intra-group differences were found among the different evaluation times ($p > 0.05$).

## Discussion

Eighteen women with TMD participated in this study, the aim of which was to analyze the effects of PBM with simultaneous administration of red (660 nm) and infrared (850 nm) LEDs in the same device on pain and mandibular range of motion in individuals with TMD. For such, a cluster composed of 36 LEDs (18 infrared and 18 red) was used in six non-consecutive sessions. The hypothesis was that the therapeutic use of a red and infrared LED cluster would modulate pain in the masticatory muscles and TMJ region and improve mandibular range of motion in individuals with TMD. The results revealed reductions in pain intensity between the pre-intervention and post-intervention evaluations as well as between the evaluation immediately after the first session and the post-intervention evaluation (after six sessions) in the LED group. However, no improvement in mandibular range of motion was found for any of the conditions analyzed.

The RDC/TMD defines a diagnosis of myofascial pain with mouth opening limitation for individuals with more than three painful sites upon palpation of the masticatory muscles, a report of facial pain on the same side as the palpation, and mouth opening without pain < 40 mm (after correction for horizontal incisal overjet), and passive stretching (maximum opening with assistance compared to opening without assistance and without pain) ≥ 5 mm [33]. The fact that only three participants in the present study (16.6%) had a diagnosis of myofascial pain with opening limitation could explain lack of changes in mandibular range of motion, as most participants did not have limited movements.

Panhoca et al. (2015) [29] conducted a study involving PBM as a therapeutic resource for TMD, comparing LED and LLLT. The authors irradiated five points (three on the TMJ, one on the masseter muscle, and one on the temporalis muscle) in eight sessions held twice a week, with evaluations immediately after the first session as well as 7 and 30 days after treatment. Groups treated with red LED (630 ± 10 nm) and infrared LED (850 ± 10 nm) were evaluated, both with radiant exposure of 18 J/cm$^2$, an output power of 150 mW, 60 s/point, and 9 J of energy per point (45 J per session). Another group was treated with LLLT (780 nm), radiant exposure of 105 J/cm$^2$, power output of 70 mW, and 4.2 J per spot. Despite using different parameters for the different types of devices, which the authors considered a limitation of the study, the three therapies achieved similar results in terms of muscle pain and mandibular range of motion. However, the study showed that therapeutic PBM with LEDs led to improvements in terms of pain relief and maximum mouth opening immediately after the first session as well as 7 and 30 days after treatment, demonstrating that PBM with LED is an attractive treatment option for individuals with TMD.

In the present study, 18 red LEDs and 18 infrared LEDs were used simultaneously, covering the anterior temporalis and masseter muscle region at the same time, with a power of 126 mW, 1200 s, and total energy of 151.2 J per application. The results revealed a significant reduction in pain intensity at the end of treatment (six sessions over 2 weeks). Panhoca et al. (2015) [29] reported similar results in individuals with TMD after 7 days of treatment. In the present investigation, no differences in mandibular range of motion were found, as only three patients had mouth opening limitation prior to treatment. In contrast, all participants in this study had limited mouth opening.

No clinical trial was found in the literature using a device similar to that employed in the present study, which enables covering both the TMJ and masticatory muscle

regions and the simultaneous irradiation of 18 points with red LEDs and 18 with infrared LEDs in an easy way. Langella et al. (2019) [24] proposed a clinical study protocol using a plate with 36 LEDs only in the infrared spectrum (780 nm), a total power of 180 mW, 0.8 J/cm$^2$, and 600 s in eight sessions. Thus, there were differences between the study cited and the present investigation with regard to the number of sessions, dosimetric parameters, and type of light sources used. Costa et al. (2021) [37] evaluated the effects of punctually infrared LED (880 nm), divided into 16 points on the face, with a power of 30 mW, 3 J/cm$^2$, and 70 s, and compared the one or two irradiation frequencies and the association of this therapy with an occlusal splint. The authors found a reduction in the groups irradiated once and two times in the post-therapy and 30 days post-therapy in comparison to initial evaluation in the pain intensity outcome. Moreover, the results of the association of LED therapy and occlusal splint showed superior results.

Herpich et al. (2017) [14] only evaluated the immediate effect of PBM using different light sources (LED and LLLT) in women in the same age group as those in the present investigation. For such, four red LEDs (640 nm), four infrared LEDs (875 nm), and super-pulsed low-level laser (905 nm) were used, with a power of 33.4 mW on each side of the face in a single session (lower than the power of 126 mW/session used in the present study), comparing different exposure times (20, 40, and 60 s). Ten points were irradiated (five on each side of the face) on the masseter (two points) and temporalis (three points) muscles. The authors performed evaluations immediately after application as well as after 24 and 48 h, reporting a reduction in pain intensity in the post-treatment evaluations in comparison to the pre-treatment evaluation, after 24 h in the group irradiated for 60 s, and especially after 48 h in the groups exposed to irradiation for 20 and 40 s. In the present study, no significant reduction in pain intensity was found immediately after the first session, but a significant reduction was found after six sessions. Herpich et al. (2017) [14] also found no effect on mandibular range of motion, which is in agreement with the present findings.

In another study involving individuals with TMD, Al-Quisi et al. (2019) [15] used only red LED (660 nm), with 1.6 J/cm$^2$, 1600 mW, and an energy of 1.6 J per second for 180 s irradiated on points of the TMJ and lateral pterygoid muscle as well as points on the masseter and temporalis muscles if the patient reported sensitivity in sessions held once per week for 4 weeks (total of four sessions). The authors found a reduction in pain evaluated using the VAS after treatment, but no change in mandibular range of motion, as occurred in the present study. The authors also found that joint sounds were resolved in all patients (100%) treated with red LED.

In a case report, Costa et al. (2017) [17] found a reduction in pain intensity assessed using the VAS after the administration of infrared LED (880 ± 20 nm) with 7 J/cm$^2$, a power of 0.03 W, and point application for 70 s/point. Despite the different dosimetric parameters used in comparison to the present investigation, both studies demonstrated a reduction in pain in individuals with TMD treated with LED. However, Costa et al. (2017) [17] warn that LED therapy on the TMJ has no effect on the etiology of temporomandibular disorder. Thus, the authors consider PBM with LED to be supportive therapy for the reduction of signs and symptoms, but the identification and elimination of etiological factors are essential to treatment.

LED as a therapeutic resource has been used for cases of muscle injury [38, 39], to increase muscle activity after the induction of fatigue [40], and in sports rehabilitation [41, 42], but its use for the treatment of TMD has been explored little. The sample size was a limitation of the present study. However, we found the cluster of LEDs as a therapeutic resource for TMD to be effective at reducing pain intensity in a short treatment period (six sessions in 2 weeks). In contrast, no statistically significant differences were found regarding mandibular range of motion. However, only three participants had considerable mouth opening limitation at the onset of the study.

## Conclusion

The use of PBM with a cluster of red (660 nm) and infrared (850 nm) LEDs administered simultaneously over the TMJ and masticatory muscle regions led to an improvement in pain intensity in individuals with TMD. There is a need for further studies on PBM using LED to determine the most effective irradiation parameters for improvements in pain and mandibular range of motion in this population.

**Author contribution** All authors contributed to the study conception and design. The planning, execution of experiments, and collection were performed by Dowglas Fernando Magalhães de Sousa, Tainá Caroline dos Santos Malavazzi, Alessandro Melo Deana, and Anna Carolina Ratto Tempestini Horliana. Data analysis was performed by Tainá Caroline dos Santos Malavazzi. Original draft preparation was written by Dowglas Fernando Magalhães de Sousa, Tainá Caroline dos Santos Malavazzi, and Raquel Agnelli Mesquita-Ferrari. Review and editing were performed by Anna Carolina Ratto Tempestini Horliana, Kristianne Porta Santos Fernandes, and Sandra Kalil Bussadori. Supervision was made by Raquel Agnelli Mesquita-Ferrari, Kristianne Porta Santos Fernandes, and Sandra Kalil Bussadori.

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**Data availability** The data that support the findings of this study are available from the corresponding author, Raquel Agnelli Mesquita-Ferrari, upon reasonable request.

## Declarations

**Ethical approval** All procedures performed were in accordance with the ethical standards of Universidade Nove de Julho (UNINOVE; process number: 2.962.857).

**Informed consent** Informed consent was obtained from all individual participants included in the study.

**Conflict of interest** The authors declare no competing interests.

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