gyptian Journal of
Physical Therapy (EJPT)

Egy. J. Phys. Ther. 2022; 12:29-37 **Original article**

https://ejpt.journals.ekb.eg

Effectiveness of Low-Level Laser Therapy and Myofascial Release Technique on Health-Related Outcomes of Pregnant Women with Temporomandibular Myofascial Pain: A Randomized Controlled Trial

Radwa Mohammed Yehia[1], Mohamed Magdy ElMeligie[2*], Ahmed Atteya Ashour[3], Gehan A. Abdelsamea [4,5]

[1]Department of Physical Therapy for Paediatrics and women health, Faculty of Physical Therapy, Ahram Canadian University, Egypt.
[2]Department of Physical Therapy for Basic Sciences, Faculty of Physical Therapy, Ahram Canadian University, Egypt.
[3]Department of Biomechanics, Faculty of Physical Therapy, October 6 University, Giza, Egypt.
[4]Department of Physical Therapy for Woman's Health, Faculty of Physical Therapy, Cairo University, Cairo, Egypt.
[5]Department of Women's Health, Faculty of Physical Therapy, Delta University for science and Technology, Gamasa, Egypt.

***Correspondence to**
Gehan A. Abdelsamea, Department of physical therapy for woman's health, Cairo University, Egypt.
Tel: 01001983333
Email:
gehan.saeed@pt.cu.edu.eg

Published online:
Dec 2022

Abstract:

Objective: This research aimed to investigate the usefulness of low-level laser therapy (LLLT) combined with myofascial release (MFR) technique for Temporomandibular myofascial pain (TMP) during pregnancy.

Methods: A randomized, controlled experiment with a prospective, double-blind design was conducted on 30 pregnant women, with a mean age of 28.2±3.4 years, at 24 weeks of pregnancy, seeking treatment for chronic TMP (lasting more than 3 months). The patients were randomly assigned into either control group (CG) who received standard treatment alone in the form of therapeutic ultrasound, hot pack and exercise program or experimental group (EG) who received the standard treatment combined with LLLT and MFR. Pain intensity and temporomandibular joint (TMJ) function as a primary outcome and pain pressure threshold (PPT) as a secondary outcome were assessed pre and post the treatment (four weeks program).

Results: Participants from both groups improved all outcomes after the treatment ($p < .001$). The EG showed better improvement in the primary outcome function compared to the CG with (MD) = -2.07 (95%CI = -3.66 to -1.59). In addition, both groups significantly increased PPT at the TMJ, Masseter and Temporal anterior muscles in both sides ($p < .001$). Although the combined treatment resulted in clinically important changes in pain intensity, this change was more prominent in participants from the control group (MD = 2.6, 95%CI = 0.3 to 1.91).

Conclusion: LLLT combined with MFR, and standard treatment is superior to standard treatment alone to reduce PPT and increase TMJ function in pregnant women with TMP.

Key words: Temporomandibular Disorders, Photo biomodulation, Manual therapy, Pain, Pregnancy care.

Please cite this article as follows: Yehia M, ElMeligie M, Ashour A, Abdelsamea A. Effectiveness of Low-Level Laser Therapy and Myofascial Release Technique on Health-Related Outcomes of Pregnant Women with Temporomandibular Myofascial Pain: A Randomized Controlled Trial. EJPT. 2022; 12:28-37.

1.Introduction:

Temporomandibular disorder (TMD) is a term for conditions that affect the muscles used for chewing, the temporomandibular joint, also other structures near the temporomandibular joint (1).

Patients with TMD may experience symptoms such as discomfort, limited jaw motion, and grinding, cracking, or clicking sounds in the TMJ. TMD symptoms are classified by symptom duration (i.e., acute or chronic) and facial location (unilateral or bilateral) (2), impairing activities of swallowing, chewing, and speaking (3-5).

The prevalence of TMD varies from 11% to 31% (6), and about 80% of patients treated for TMD are women between 20-40 years of age (7). Approximately 72% of pregnant women can have significant signs of TMD (8). Identifying the cause of TMD is an arduous task (2). However, myofascial pain disorder is the most common cause of TMD (9). The psychological distress associated with pregnancy and the marked rise of hormone levels such as estrogen, progesterone and relaxin that increases joint laxity (10) and several specific inflammatory responses in the TMJ (11) may predispose TMP.

Although TMP is common during pregnancy and postpartum (12), this population is under-investigated in clinical research (13). Thus, most recommendations for treatments for TMP are from the general population (14-16). A significant number of studies explored the usefulness of low-level laser therapy for TMD showing better results compared to placebo, occlusive splint or no intervention (waiting list) (17-20). However, information about the effectiveness and safety of LLLT for pregnant women with TMP is lacking. In addition, despite TMP being frequently found among patients with TMD (21, 22), evidence of effectiveness of the myofascial release technique (MFR) for TMP is insufficient.

MFR is a type of manual therapy that involves stretching the myofascial complex with low loads and for long periods of time. The objective is to regain optimal tissue length, flexibility, and sliding of myofascial mobility in order to reduce pain and improve function. (23, 24). MFR may also relief the aching and increase the range of motion of body joints by releasing bonds between fascia and skin, muscles, and bones (25).

Thus, based on the previous findings of the efficacy of LLLT for temporomandibular complaints and the effects of MFR on permanent muscle adaptation, reduction in tissue swelling, pain, tension headaches, and muscle aches and relief of the masseter tension (26), we hypothesized that a combined treatment with LLLT and MFR can improve TMP symptoms during pregnancy. Therefore, the purpose of this research is to examine the efficacy of conventional treatments for TMP in pregnant women with the addition of low-level laser therapy and myofascial release.

2.Patients and Methods:

2.1. Study Design:

A two-arm; assessor and therapist blinded randomized controlled trial was conducted in pregnant women with chronic temporomandibular disorder. Participants were recruited among those seeking care at the physiotherapy clinic of October 6 University Hospital, Egypt. The study's objectives were explained to all eligible women. A consent form was signed by all eligible women in the study. Before randomization, a consultant orthodontist first established eligibility, which was then verified by the therapists and a board-certified osteopath.

An independent researcher (not involved in data collection) generated a random order of allocation codes using a website (https://www.randomizer.org/) and then randomly assigned participants to either EG or CG. The randomization codes were located in numbered, sealed, opaque envelopes to protect the allocation list (27). The EG received myofascial release and low-level laser therapy combined with standard treatment, while the CG was given only the normative intervention. The study's interventions were provided to all participants at the same clinic over the course of four weeks, and the results were obtained from all visits to that location. Consolidated Standards of Reporting Trials guidelines were used to write up this study (28).

Clinical Trials Registration Number: NCT05138354 was assigned to the study's protocol. Prior to the start of the study, it was reviewed and given the all-clear by the Physical Therapy department's institutional reviewing board at Cairo University (No: P.T.REC/012/002983).

2.2. Participants:

30 pregnant women at 24 weeks pregnancy, age range from 20 to 35 years (mean age of 28.2±3.4 years) presenting chronic bilateral TMD (> 3 months) were recruited between (February/2021 to October/2021). Following the Research Diagnostic Criteria for Temporomandibular Disorders, individuals needed to have a TMD including myofascial component in order to be considered for participation (29). Participants were not allowed to take part in the study if they had facial neuro-musculoskeletal pathologies (such as trauma of the face /or fractures and bell's palsy), acute infectious diseases or systemic illnesses, osteoporosis, neck or upper limb impairment, drug infiltration, any recent cure taken or surgery over TMJ, hypermobile TMJ, or neurological disorders. During the course of the trial, participants were requested to refrain from

taking any prescription drugs in order to manage their pain or bring down their inflammation levels.

2.3. Interventions:

Patients in both groups were given a course of therapy lasting for 4 weeks (Approximately 12 sessions of treatment, three times per week, for 60 minutes). Ultrasound, hot pack administration, and exercise were all part of the standard treatment plan that was followed by all of the patients. Participants in the EG group also had myofascial release and low-level laser therapy in addition to the standard treatment. All interventions took place at the physiotherapy outpatient clinic at of October 6 University Hospital, Egypt. The TIDieR checklist and guide are used to accurately define interventions (30).

2.4. Procedures:

A certified osteopath applied the MFR technique. Patients were placed in a supine position on a treatment table for this technique. A gross release treatment for the masseter and pterygoids muscles is applied by the therapist, who is seated next to the patient at the side of the afflicted temporomandibular joint. The therapist employed the treatment for 90 sec for each site five times throughout the session (five sec of rest between each repetition). When administering the intraoral myofascial release, the therapist wore gloves. In the event that the patient reported a latex allergy, the gloves were replaced with latex-free alternatives.

To perform MFR for masseter muscle, the patient was lying supine while the therapist inserted his index finger into the patient's mouth between the cheek and the teeth. Then the therapist forced his index finger in a posterosuperior portion of the masseter muscle and asked the patient to open his mouth wider and gently close until the tissue softens.

To perform the MFR of the masseter muscle, the therapist inserted his index finger onto the Coronoid process of the mandible, applying gentle posteroinferior pressure while the other hand's index and middle fingers applied a superior pressure along the fibers of the temporalis muscle. Patients are instructed to gently open their mouths as wide as possible and then close them again. The pressure applied was unable to aggravate the pain response.

During release of medial pterygoid procedure, the patient lied in a supine position with the mouth opened wide. The therapist inserted his index finger just behind the upper molars and followed inside the upper gum-line back while applying a steady pressure at the superior attachment of the medial pterygoid muscle. Later, the therapist followed inside the lower gum-line back, just behind the lower molars, to the angle of the ramus. The patient was asked to breathe normally during the release. While performing the release, the therapist avoided contacting the Pterygoid Hamulus.

During release of lateral pterygoid with the patient lying supine with the mouth opened wide, the therapist slid his index finger along the outside area of the patient's upper teeth to the back edge of the last molar. The patient was asked to move the jaw towards the side where the therapist was applying the MFR. This maneuver aimed to increase the space between the coronoid process and the teeth. During the release, the therapist applied a steady, slow, and receptive pressure to the lateral pterygoid muscle while asking the patient for small opening and closing movements to facilitate the release.

2.4.1. Low-level laser therapy session:

A specialist in applying laser therapy (MM) used an MLS® device (*ASA Srl, Vicenza, Italy*) Infrared laser therapy using a pair of synchronized light sources (laser diodes) with a wavelength of 808 nm. Irradiation was administered to four sites on the mandibular condyle (front, back, and over) and the external auditory meatuses by holding the laser probe vertically in contact with the skin. A laser beam with a diameter of 3.14 cm^2, a pulse rate of 1500 Hz, pulse duration of 100ms, and an energy density of 16 J/cm2 was used to irradiate the area for 14 seconds at each location.

2.4.2. Standard treatment:

2.4.2.1. Ultrasound :

Participants were exposed to pulsed ultrasound with a frequency of three MHz, an intensity of 0.5 W/cm^2, and a duty cycle of 1:1. The therapist applied gentle circular motions to the TMJ for a full 6 minutes using a Phyaction Ub (*Gymna Uniphy, GY336600, Italy*) equipped with a transducer of just 4 cm^2 in diameter.

2.4.2.2. Hot pack:

The participants got a warm water pack (13x30 cm) heated to 38–40°C and wrapped in a towel. It was placed on the area around their TMJ and jaw muscles for 10 minutes.

2.4.2.3. Exercise Regimen:

Mandibular muscle exercises were utilized to actively adjust the jaw position and hence the mouth opening. Opening the mouth as wide as you can, protruding the jaw to the right and left, (three sets of ten repetitions). Jaw relaxation technique: Mouth opening with the tongue held posterior to the upper front teeth while relaxing the jaw muscles (three sets of ten repetitions). Chin tucks exercise: The patient was taught to pull the chin straight back towards the cervical spine while maintaining a tense, double-chin inducing back-shoulder posture (ten repetitions, with holding ten sec each). Resisted opening of the mouth exercise: The patient was instructed to position his

thumb under his chin and begin slowly opening his mouth against gentle thumb resistance.

After 3 seconds of holding, the therapist had the patient slowly close their mouth (three sets of ten repetitions). Resisted closing of the mouth exercise: Patient was told to open his mouth and then close it while placing light pressure on his chin using their index also thumb of one hand (three sets of ten repetitions).

Jaw muscle stretching: the patient was instructed to hold her mouth open and use her thumb to press her lower teeth down, which would stretch her mandibular muscles (4 sets per session, 3 repetitions of 30 seconds) (18)**.**

2.5. Health related Outcomes:

2.5.1. Visual analogue scale (VAS:)

Pain intensity in the temporomandibular joint and pain pressure threshold (PPT) were taken bilaterally before treatment began and again right after the fourth and final session.

The VAS, a validated subjective measure for both acute and chronic pain, was used to quantify temporomandibular pain intensity (31, 32). At the time of the evaluation, patients were asked to mark a 10-centimeter ruler on a scale from 0 (no pain) to 10 (worst agony imaginable) to indicate their level of discomfort. The primary result was the degree of pain, which was evaluated before therapy and again after four weeks.

2.5.2. Pressure algometer:

A blinded assessor used an algometer (FPX 25, Wagner Instruments, Greenwich CT, USA), an instrument for measuring pressure or applied force on any region of the body in order to record pressure pain threshold (PPT) before and after therapy. PPT is a secondary outcome. A participant was asked a series of questions by an evaluator to seat in an upright position with the head supported by a headrest, muscles of the jaw relaxed and teeth apart. With the patient positioned the assessor marked 3 points bilaterally at the TMJ, masseter muscles and anterior temporalis muscles. Assessors measured PPT by pressing down at a rate of about 5 N/s on the skin with a circular tip of the instrument (1 cm^2 in area). Each participant was instructed to signal with a raised hand when the first feeling of compression or discomfort developed into a painful experience.

A single measurement was performed at each place from both sides. The proximal insertion of the dominant side's wrist extensor muscle was used for two demonstrations by the assessor before the first measurement was taken to verify the subject understood the test. The evaluator gave a second demonstration if the participant had any remaining concerns.

2.5.3. Limitations of daily function in temporomandibular disorder questionnaire:

The limitations of daily functions in temporomandibular disorder questionnaire (LDF-TMDQ) were employed to evaluate the functioning of the participants. Patients were asked to rate how much their jaw condition affected their ability to carry out a set of ten commonly performed tasks in order to assess jaw function, which was considered the primary outcome (33).

Each task is assigned a value from 0 (no issue at all) to 4 (very difficult), with the participant selecting a level in between. The sum of the ten items was calculated, with possible points ranging from 0 to 40.

2.6. Data analysis:

The Shapiro-Wilk test was utilized to verify the data's normality. Descriptive statistics were used to report on the subjects' characteristics. Paired-samples t-tests were used to determine significant differences within groups, as well as their 95% confidence intervals (CI). (Level of significance, $p < 0.05$).

Mixed design MANOVA was used to determine the treatment effects (i.e., the mean between-group differences) and the 95% confidence intervals. Interaction terms represent the same thing as between-group variance. Alterations within and across groups were evaluated using the Kruskal-Wallis and Wilcoxon signed rank tests, respectively. Since all participants finished the entire intervention, we did not conduct an intention-to-treat interpretation. SPSS (SPSS Inc., Chicago, IL) version 23 was used for the analyses, and the threshold for significance was set at 5%.

3.Results:

At the baseline, there were no differences in age, weight, or height between the groups ($p>0.05$), so the groups were well-matched **(Table 1).** Recruiting, excluding, assessing, and intervening are all depicted in considerable detail in **Figure 1.**

Pain levels and the interference of TMD with daily activities were both shown to decrease in both groups **(Table 2).** The remaining differences favored the experimental group **(Table 3).**

In addition, both groups had increased pain pressure threshold at the TMJ, Masseter and Temporal anterior muscles in the right and left sides with TMJ in the right (MD = 0.98, 95%CI 0.71 to 1.25) and left side (MD = 0.51 0.31 to 0.70), Masseter in the right (MD = 0.52, 95%CI 0.34 to 0.7) and left side (MD = 0.41, 95%CI 0.23 to 0.58), and at the left side of the temporalis anterior muscle (MD = 0.15, 95%CI 0.02 to 0.2) (**Table 4**). The estimate of the effect for pain intensity was higher in the group that received standard treatment when

compared with the experimental group: MD 2.6 points (95% CI= 0.3 to 1.91).

4.Discussion:

This trial investigated the effects of low-level laser therapy and myofascial release combined with standard treatment (thermotherapy, ultrasound and exercises) on chronic temporomandibular myofascial pain during pregnancy. We hypothesized that adding MFR and LLT to a standard intervention in patients with TMD with a myofascial component would provide better results than offering the standard treatment alone. To our knowledge, this is the first RCT to show an improvement in TMJ function and PPT in pregnant women with chronic TMP. After receiving the therapies, participants in both groups reported a marked decrease in pain intensity and improvement in their ability to perform daily tasks. The pain had been reduced more in the CG group, while the EG group had more improvements in function.

Table (1): Descriptive statistics and unpaired t-tests for the mean age, weight and height for both groups.

Variables	Experimental group (n = 15)	Control group (n = 15)	P-value
Age	28.33 ± 3.68	28.13 ± 3.25	0.876
Weight (kg)	83.73 ± 4.55	84.2 ± 3.27	0.750
Height (cm)	165.8 ± 2.9	166.53 ± 2.55	0.470

***Significance (P<0.05).**

Table (2): Mean and standard deviation (SD) of the baseline and post treatment parameters of pain, function and PPT in the EG, and within-group difference (mean, SD).

Variables	Baseline (n = 15)	Post treatment (n = 15)	Mean difference (SD) Post treatment – baseline	P value
VAS (0-100)	7.00 (1.93)	4.67 (2.99)	-2.33 (1.95)	< .001
LDF-TMDQ (0 to 40)	14.30 (2.13)	7.73 (0.80)	-6.57 (2.13)	< .001
TMJ (R)	1.97 (0.28)	3.43 (0.41)	1.46 (0.51)	< .001
TMJ (L)	1.84 (0.24)	2.90 (0.29)	1.06 (0.31)	< .001
Masseter (R)	2.50 (0.33)	3.67 (0.27)	1.17 (0.27)	< .001
Masseter (L)	2.60 (0.24)	3.62 (0.25)	1.02 (0.14)	< .001
Temporalis anterior (R)	4.01 (0.27)	4.62 (0.19)	0.61 (0.22)	< .001
Temporalis anterior (L)	4.25 (0.23)	4.73 (0.18)	0.48 (0.16)	< .001

Significance level (P<0.05)

Table 3: Mean and standard deviation (SD) of the baseline and post treatment parameters of pain, function and PPT in the CG and within-group difference (mean difference, SD)

Variables	Baseline (n = 15)	Post treatment (n = 15)	Mean difference (SD) Post treatment – baseline	P-value
VAS (0-100)	7.60 (2.03)	2.07 (1.49)	-5.53 (1.59)	< .001
LDF-TMDQ (0 to 40)	14.30 (1.33)	9.80 (0.77)	-4.5 (1.19)	< .001
TMJ (R)	1.89 (0.24)	2.45 (0.29)	0.56 (0.13)	< .001
TMJ (L)	1.9 (0.21)	2.39 (0.21)	0.49 (0.12)	< .001
Masseter (R)	2.57 (0.25)	3.15 (0.21)	0.59 (0.19)	< .001
Masseter (L)	2.75 (0.22)	3.21 (0.23)	0.47 (0.07)	< .001
Temporalis anterior (R)	4.12 (0.18)	4.49 (0.15)	0.37 (0.15)	< .001
Temporalis anterior (L)	4.29 (0.22)	4.58 (0.17)	0.29 (0.19)	< .001

Significance level (P<0.05)

Table 4: Mean and standard deviation (SD) of the post treatment parameters of pain function and PPT of both groups with between-group difference (mean difference, 95%CI)

Variables	Experimental (n = 15)	Control (n = 15)	Mean difference (95%CI) Experimental - Control	P-value
VAS (0-100)	4.67 (2.99)	2.07 (1.49)	2.6 (0.3 to 1.91)	0.005
LDF-TMDQ (0 to 40)	7.73 (0.80)	9.80 (0.77)	-2.07 (-3.66 to -1.59)	< .001
TMJ (R)	3.43 (0.41)	2.45 (0.29)	0.98 (0.71 to 1.25)	< .001
TMJ (L)	2.90 (0.29)	2.39 (0.21)	0.51 (0.31 to 0.70)	< .001
Masseter (R)	3.67 (0.27)	3.15 (0.21)	0.52 (0.34 to 0.7)	< .001
Masseter (L)	3.62 (0.25)	3.21 (0.23)	0.41 (0.23 to 0.58)	< .001
Temporalis anterior (R)	4.62 (0.19)	4.49 (0.15)	0.13 (-0 to 0.2)	0.05
Temporalis anterior (L)	4.73 (0.18)	4.58 (0.17)	0.15 (0.02 to 0.2)	0.02

Significance level (P<0.05)

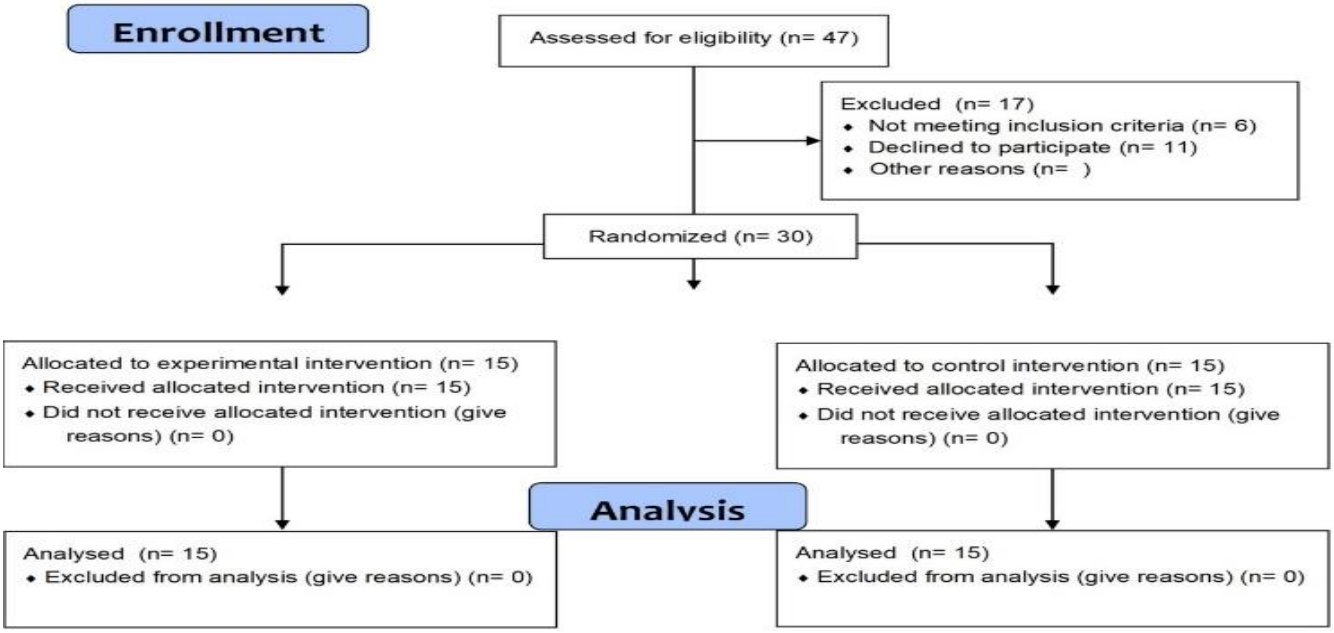

Figure 1: Flow of participants through the trial.

Participants from the EG presented improvements in pain intensity, functionality, and pressure pain threshold that surpassed the minimum clinically important difference (34). Because both groups presented high pain intensity (≥ 7 out of 10 points) at the baseline, we cannot discharge the possible contribution of the effect of the regression to the mean and other contextual effects to the improvements (35).

TMD is a multifactorial condition and diagnosing the etiologic factors can be difficult (36). Thus, treatments are usually nonspecific, causing unsatisfactory and conflicting results (37, 38). Pregnant women may represent a specific subgroup that presents TMD due to a myofascial component. In these individuals, interventions targeting the myofascial component as those used in this trial are may responsible for the significant improvements found in the experimental group. However, we are unaware of any previous RCT targeting pregnant women with TMD preventing us from comparing our findings with similar studies. Previous evidence supports that exclusion of pregnant women from clinical trials for TMD can be related to a misbelief that temporomandibular symptoms present during pregnancy will disappear in the postpartum (12).

The addition of low-level laser therapy and myofascial release to standard treatment resulted in extra improvements to all outcomes, except pain intensity compared to standard care alone. The effectiveness of exercise alone in treating TMD is controversial. In a systematic review, Dickerson et al. (38) found that exercise therapies did not improve pain or function in individuals with TMD. Furthermore, the outcomes of a randomized controlled trial comparing an eight weeks program of localized endurance exercises for the masticatory muscles with a placebo (sham laser) showed a reduction in pain scores for both groups with lower pain values on the placebo group at short-term (37). Moreover, the authors found no differences between groups for PPT (37).

Although TMDs have a myofascial component (29), the mechanisms of action and effectiveness of the MFR technique on these patients are still unclear (15, 39). Based on the results of a systematic review (15), there is moderate evidence that MFR is better than placebo or no intervention to improve the mouth opening. Findings of an RCT comparing intra-oral MFR technique with self-exercise showed that patients from both groups experienced pain reduction after 5 weeks of intervention without further differences between the groups (39). On the other hand, there is a significant amount of research investigating the effectiveness of LLLT on TMDs (17,18,20,40).

Low-level laser therapy has shown to be effective for pain modulation and improve function in patients with TMD (40). Furthermore, the number of tender points and the intensity of pain can both be reduced with LLLT and facilitate an active range of motion (41). In addition, LLLT combined with standard therapy increases the PPT, and Symptoms of pain that interfere with regular activities (42). Furthermore, the addition of oral motor exercises to LLLT enhances TMJD management instead of LLLT alone (43). Also, there is evidence that high doses of LLLT may cause additional improvements in TMD outcomes (44).

According to the biopsychosocial model of health, the rehabilitation of chronic conditions must aim to improve pain, function, and psychological

health (45, 46). However, it is common to find patients with chronic conditions receiving treatments that do not target function, ending when pain resolves. Although these patients may experience a reduction in pain, the dysfunction continues, and the patient remains with limitation in daily activities (47). Because of this, our results lend credence to the hypothesis that chronic pain patients may benefit more broadly from a multimodal approach that simultaneously addresses multiple aspects of their health.

Strengths and limitations:

This study's strength is that it took all the required steps to lessen the possibility of bias. These steps included using appropriate randomization processes, concealing allocation, blinding the assessor and therapist, and ensuring that the groups were similar at baseline. A weakness of the study is that we assessed only the immediate effect of the interventions after the end of the 4 weeks intervention program. A long-term follow-up could show sustained improvements and provide an idea about how much of the pain change was due to time fluctuation and regression to the mean effect. The fact that participants in the control group did not receive the MFR and were free of the muscle load and stretches demanded from the technique may contribute to this group feeling additional pain decrements in the short term. Because we targeted pregnant women, our results may not be generalized to other populations with TMP.

5.Conclusion:

Low-level laser therapy combined with myofascial release techniques and a standard treatment comprised of ultrasound, thermotherapy and exercises can provide clinically important improvements in pain, pain pressure threshold and function in pregnant women with TMP. Standard treatment alone could only reduce pain but was more effective than the combined treatment to improve this outcome.

Ethical consideration:

The study protocol was registered at the Clinical Trials Registry NCT05138354. The study was approved by the institutional review board at faculty of physical therapy, Cairo University, before its commencement No: P.T.REC/012/002983. All eligible women who agreed to participate in the study signed a consent form.

Funding:

Not funded.

Conflict of Interests:

Authors declare no potential conflicts of interest.

Acknowledgments:

We would like to thank all individuals who contributed to the completion of this work, especially participants.

References:

1. Report of the president's conference on the examination, diagnosis, and management of temporomandibular disorders. Journal of the American Dental Association 1983;106(1):75–7.
2. Harrison AL, Thorp Jn Fau - Ritzline PD, Ritzline PD. A proposed diagnostic classification of patients with temporomandibular disorders: implications for physical therapists. The Journal of orthopaedic and sports physical therapy. 2014;44(3):182–97.
3. Gilheaney Ó, Stassen, L. F., & Walshe, M. The epidemiology, nature, and impact of eating and swallowing problems in adults presenting with temporomandibular disorders. Cranio : the journal of craniomandibular practice. 2020(2151-0903 (Electronic)):1–9.
4. Ferreira C, Sforza C, Rusconi F, Castelo P, Bommarito S. Masticatory behavior and chewing difficulties in young adults with temporomandibular disorders. Journal of Oral Rehabilitation. 2019;46.
5. Pereira TC, Brasolotto AG, Conti PC, Berretin-Felix G. Temporomandibular disorders, voice and oral quality of life in women. J Appl Oral Sci. 2009;17 Suppl(spe):50-6.
6. Valesan LA-O, Da-Cas CD, Réus JC, Denardin ACS, Garanhani RR, Bonotto D, et al. Prevalence of temporomandibular joint disorders: a systematic review and meta-analysis. Clinical oral investigations. 2021;25(2):441–53.
7. Patil S, Yadav N, Mousa M, Alzwiri A, Kassab M, Sahu R, et al. Role of female reproductive hormones estrogen and progesterone in temporomandibular disorder in female patients. Journal of Oral Research and Review. 2015;7(2):41-3.
8. Fichera G, Polizzi A, Scapellato S, Palazzo G, Indelicato F. Craniomandibular Disorders in Pregnant Women: An Epidemiological Survey. J Funct Morphol Kinesiol. 2020;5.(2)
9. Chapter 10 - Temporomandibular Joint Disorders. In: Bagheri SC, editor. Clinical Review of Oral and Maxillofacial Surgery (Second Edition). St. Louis (MO): Mosby; 2014. p. 333-51.
10. Anselmo S, Love, E., Tango, D. N., Robinson, L. Musculoskeletal Effects of Pregnancy on the Lower Extremity (A Literature Review). Journal

of the American Podiatric Medical Association. 2017;107(1): 60–4.
11. Chang CL, Wang DH, Yang MC, Hsu WE, Hsu ML. Functional disorders of the temporomandibular joints: Internal derangement of the temporomandibular joint. The Kaohsiung journal of medical sciences. 2018;34(4):223–30.
12. LeResche L, Sherman JJ, Huggins K, Saunders K, Mancl LA, Lentz G, et al. Musculoskeletal orofacial pain and other signs and symptoms of temporomandibular disorders during pregnancy: a prospective study. J Orofac Pain. 2005;19(3):193-201.
13. Lyerly AD, Little MO, Faden R. The second wave: Toward responsible inclusion of pregnant women in research. Int J Fem Approaches Bioeth. 2008;1(2):5-22.
14. Zhang C, Wu JY, Deng DL, He BY, Tao Y, Niu YM, et al. Efficacy of splint therapy for the management of temporomandibular disorders: a meta-analysis. Oncotarget. 2016;7(51):84043–53.
15. Calixtre LB, Moreira RF, Franchini GH, Alburquerque-Sendín F, Oliveira AB. Manual therapy for the management of pain and limited range of motion in subjects with signs and symptoms of temporomandibular disorder: a systematic review of randomised controlled trials. Journal of oral rehabilitation 2015;42(11):847–61.
16. Shimada AA-O, Ishigaki SA-OX, Matsuka YA-O, Komiyama OA-O, Torisu TA-O, Oono YA-O, et al. Effects of exercise therapy on painful temporomandibular disorders. Journal of oral rehabilitation. 2019;46(5):475–81.
17. Maia M, Bonjardim L, Quintans J, Ribeiro M, Maia L, Conti P. Effect of low-level laser therapy on pain levels in patients with temporomandibular disorders: A systematic review. J Appl Oral Sci. 2012;20:594-602.
18. Madani A, Ahrari F, Fallahrastegar A, Daghestani N. A randomized clinical trial comparing the efficacy of low-level laser therapy (LLLT) and laser acupuncture therapy (LAT) in patients with temporomandibular disorders. Lasers in medical science. 2020;35.(1)
19. Shousha TA-O, Alayat M, Moustafa I. Effects of low-level laser therapy versus soft occlusive splints on mouth opening and surface electromyography in females with temporomandibular dysfunction: A randomized-controlled study. PloS one. 2021;16(10): e0258063.
20. Munguia FM, Jang, J., Salem, M., Clark, G. T., Enciso, R. Efficacy of Low-Level Laser Therapy in the Treatment of Temporomandibular Myofascial Pain: A Systematic Review and Meta-Analysis. Journal of oral & facial pain and headache. 2018;32(3):287–97.
21. Perschbacher S. Chapter 27 - Temporomandibular Joint Abnormalities. In: White SC, Pharoah MJ, editors. Oral Radiology (Seventh Edition). St. Louis (MO): Mosby; 2014. p. 492-523.
22. Furquim BD, Flamengui LM, Conti PC. TMD and chronic pain: a current view. Dental press journal of orthodontics. 2015;20(1):127–33.
23. Trivedi P, Bhatt P, Dhanakotti S, Nambi G. Comparison of muscle energy technique and myo fascial release technique on pain and range of motion in patients with tempero mandibular joint dysfunction. International Journal of Physiotherapy and Research. 2016;4:1788-92.
24. Ajimsha MS, Al-Mudahka NR, Al-Madzhar JA. Effectiveness of myofascial release: systematic review of randomized controlled trials. Journal of bodywork and movement therapies. 2015;19(1):102–12.
25. Namvar H, Olyaei G, Moghadam B, A.,, Hosseinifar M. "Effect of myofascial release technique on pain, disability, maximum isometric contraction of the extensor muscles, and pressure pain threshold in patients with chronic nonspecific neck pain: Double blinded randomized clinical trial". International J Medical Research & Health Sciences. 2016; 5(7S):500-6.
26. Wieckiewicz M, Boening K, Wiland P, Shiau YY, Paradowska-Stolarz A. Reported concepts for the treatment modalities and pain management of temporomandibular disorders. The journal of headache and pain. 2015;16.(106)
27. Schulz KF, Grimes DA. Allocation concealment in randomised trials: defending against deciphering. Lancet. 2002;359(9306):614–8.
28. Moher D, Schulz KF, Altman DG. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomised trials. The Lancet. 2010;357(9263):1191-4.
29. Schiffman E, Ohrbach, R., Truelove, E., Look, J., Anderson, G., Goulet, J. P., List, T., Svensson, P., Gonzalez, Y., Lobbezoo, F., Michelotti, A., Brooks, S. L., Ceusters, W., Drangsholt, M., Ettlin, D., Gaul, C., Goldberg, L. J., Haythornthwaite, J. A., Hollender, L., Jensen, R. Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) for Clinical and Research Applications: recommendations of the International RDC/TMD Consortium Network* and Orofacial Pain Special Interest Group†. Journal of oral & facial pain and headache, 2014;28(1):6-17.

30. Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ : British Medical Journal. 2014;348.
31. McCormack HM, Horne Dj Fau - Sheather S, Sheather S. Clinical applications of visual analogue scales: a critical review. Psychological medicine. 1988; 18(4):1007–19.
32. Bijur PE, Silver W Fau - Gallagher EJ, Gallagher EJ. Reliability of the visual analog scale for measurement of acute pain. Academic emergency medicine : official journal of the Society for Academic Emergency Medicine. 2001;8(12):1153–7.
33. Sugisaki M, Kino K Fau - Yoshida N, Yoshida N Fau - Ishikawa T, Ishikawa T Fau - Amagasa T, Amagasa T Fau - Haketa T, Haketa T. Development of a new questionnaire to assess pain-related limitations of daily functions in Japanese patients with temporomandibular disorders. Community dentistry and oral epidemiology 2005;33(5):384–95.
34. Calixtre LB, Oliveira AB, Alburquerque-Sendín F, Armijo-Olivo S. What is the minimal important difference of pain intensity, mandibular function, and headache impact in patients with temporomandibular disorders? Clinical significance analysis of a randomized controlled trial. Musculoskeletal science & practice, 2020;46.(102108)
35. Morton V, Torgerson DJ. Regression to the mean: treatment effect without the intervention. Journal of Evaluation in Clinical Practice. 2005;11(1):59-65.
36. Chisnoiu AM, Picos AM, Popa S, Chisnoiu PD, Lascu L, Picos A, et al. Factors involved in the etiology of temporomandibular disorders - a literature review. Clujul Med. 2015;88(4):473-8.
37. Barbosa MA, Tahara AK, Ferreira IC, Intelangelo L, Barbosa AA-O. Effects of 8 weeks of masticatory muscles focused endurance exercises on women with oro-facial pain and temporomandibular disorders: A placebo randomised controlled trial. Journal of oral rehabilitation. 2019;46(10):885–94.
38. Dickerson SM, Weaver JM, Boyson AN, Thacker JA, Junak AA, Ritzline PD, et al. The effectiveness of exercise therapy for temporomandibular dysfunction: a systematic review and meta-analysis. Clinical Rehabilitation. 2016;31(8):1039-48.
39. Kalamir A, Graham PL, Vitiello AL, Bonello R, Pollard H. Intra-oral myofascial therapy versus education and self-care in the treatment of chronic, myogenous temporomandibular disorder: a randomised, clinical trial. Chiropractic & Manual Therapies. 2013;21(1):17.
40. Xu GZ, Jia J, Jin L, Li JH, Wang ZY, Cao DA-O. Low-Level Laser Therapy for Temporomandibular Disorders: A Systematic Review with Meta-Analysis. Pain research & management. 2018;4230583(1918-1523 (Electronic)).
41. Sayed N, Murugavel C, Gnanam A. Management of Temporomandibular Disorders with Low Level Laser Therapy. J Maxillofac Oral Surg. 2014;13(4):444-50.
42. Ahmad R, Mohamed Abd Elatief E, Sayed W, Ali R, Ashour E, Abdelsamee M. Effect of conventional therapy and low-level laser therapy on pain and limitations of daily functions in patients with temporomandibular joint dysfunction. International Journal of Physiotherapy and Research. 2018;6:2797-805.
43. Machado BC, Mazzetto MO, Da Silva MA, de Felício CM. Effects of oral motor exercises and laser therapy on chronic temporomandibular disorders: a randomized study with follow-up. Lasers in medical science 2016;31(5):945–54.
44. Santos T, Piva, M. R., Ribeiro, M. H., Antunes, A. A., Melo, A. R., Silva, E. D. Lasertherapy efficacy in temporomandibular disorders: control study. Brazilian journal of otorhinolaryngology, 2010; 76(3):294–9.
45. Su N, Lobbezoo F, van Wijk A, van der Heijden GJMG, Visscher CM. Associations of pain intensity and pain-related disability with psychological and socio-demographic factors in patients with temporomandibular disorders: a cross-sectional study at a specialised dental clinic. Journal of Oral Rehabilitation. 2017;44(3):187-96.
46. Lin I, Wiles L, Waller R, Goucke R, Nagree Y, Gibberd M, et al. What does best practice care for musculoskeletal pain look like? Eleven consistent recommendations from high-quality clinical practice guidelines: systematic review. British Journal of Sports Medicine. 2020;54(2):79.
47. Runge N, Aina A, May S. Are within and/or between session improvements in pain and function prognostic of medium and long-term improvements in musculoskeletal problems? A systematic review. Musculoskeletal science & practice 2020;45(102102.).