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The effectiveness of exercise therapy for temporomandibular dysfunction: a systematic review and meta-analysis

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Abstract

Objective: To investigate the effectiveness of exercise therapy on pain, function, and mobility outcomes in patients with temporomandibular joint dysfunction.

Study design: Systematic review with meta-analysis.

Methods: A systematic review and meta-analysis undertaken following Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines. Studies that met the inclusion criteria: (1) randomized controlled trials; (2) a population with the diagnosis of temporomandibular joint dysfunction; and (3) interventions that included exercise therapy were considered for review. When studies demonstrated homogeneity on outcome measures, the mean differences or standardized mean differences with 95% confidence interval were calculated and pooled in a meta-analysis for pooled synthesis.

Results: Six articles with a total of 419 participants were included in the review and only four studies were included in the meta-analysis. Mobility and mixed exercise therapy approaches appear to be the most common exercise approaches utilized for management of temporomandibular joint dysfunction. Exercise therapy and the associated dosage provide moderate short-term and varying long-term benefits in reduction of pain and improvement of range of motion of the in patients with temporomandibular joint dysfunction.

Conclusion: Included studies suggest a mobility or a mixed approach to exercise therapies have impact on reducing pain, significant impact for increasing range of motion, but lack a significant impact for functional improvement.

Level of evidence: Therapy, level 1a-.

Keywords

Temporomandibular dysfunction, rehabilitation interventions, exercise, systematic review, meta-analysis

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Introduction

Temporomandibular joint disorder is an umbrella term that encompasses several conditions involving the masticatory muscle disorders, disc displacements, and joint dysfunctions of the temporomandibular joint.[1] Pain is the most common and limiting clinical manifestation of this disorder, as well as decreased mobility of the jaw, both of which impacts quality of life.[2,3] The multifactor etiology of temporomandibular joint disorders often requires multidisciplinary healthcare professionals to manage difficult symptoms, including chronic pain.

Many studies have identified a variety of conservative interventions, such as physical therapy, for patients with temporomandibular joint disorders, including joint mobilization, tissue mobilization, dry needling, friction massage, patient education, splints, modalities, stretching, coordination activities, strengthening exercises, and combinations of these techniques.[4–8]

Previous literature demonstrates inconsistent results of effects of these interventions, specifically that of exercise therapy.[6–8] One systematic review and meta-analysis[4] addressed the gap in the literature and examined the effectiveness of manual therapy and therapeutic exercise interventions compared with a placebo or other means of conservative management for temporomandibular joint disorders. This study failed to examine specific exercise regimes of included studies to determine the most appropriate exercise parameters. Moreover, this study included 27 articles that included participants with diagnosis of temporomandibular joint disorders based on signs and symptoms determined by authors rather than specific diagnostic criteria.[4]

Exercise programs are one of the various types of interventions for treating patients with temporomandibular joint dysfunction, and may include aerobic, stretching, balance, motor control, coordination, and strengthening. Within other body regions, exercise therapy interventions have been detailed and summarize the efficacy of treatment approaches. Strengthening, stretching/flexibility, and motor control exercises have demonstrated to be efficacious in reducing pain and disability in patients with chronic low back pain,[9] as well as mechanical neck pain.[8] Despite a review and meta-analysis,[4] the efficacy of exercise therapy and dosage has yet to be determined for patients with temporomandibular joint dysfunction.

The purpose of this systematic review and meta-analysis was to examine the current literature on the effectiveness of exercise therapies for treatment of individuals with temporomandibular joint dysfunction. To our knowledge, no prior review exploring exercise therapies for temporomandibular joint dysfunction has included adherence and dosage as parameters of investigation. As a secondary aim, we wanted to determine the appropriate dosage parameters and track patient adherence to exercise programs in an effort to identify the most effective exercise prescription.

Methods

Literature search

The PRISMA Guidelines[10] were utilized as a review protocol to provide a methodical descriptive systematic review. A bibliographical search was conducted through two electronic databases: PubMed (two search strategies) and CINAHL. The development of computerized searches was with the assistance of a bioinformatics librarian. The first PubMed search strategy is outlined in Appendix 1 (available online) and was performed using Medical Subject Headings (MeSH) terms, text words, and keywords for two concepts: Temporomandibular joint disorders and exercise therapy. In addition, a search of the gray literature (hand search) was performed of the reference lists of included articles and previously published reviews. This review began 25 November 2014, with the final search completed on 19 May 2016.

Study selection

Two reviewers independently screened titles, followed by abstracts, while full text articles were reviewed for eligibility by two other authors. If either pair of initial reviewers did not achieve a consensus during the literature review process (Figure 1), a third reviewer determined inclusion/

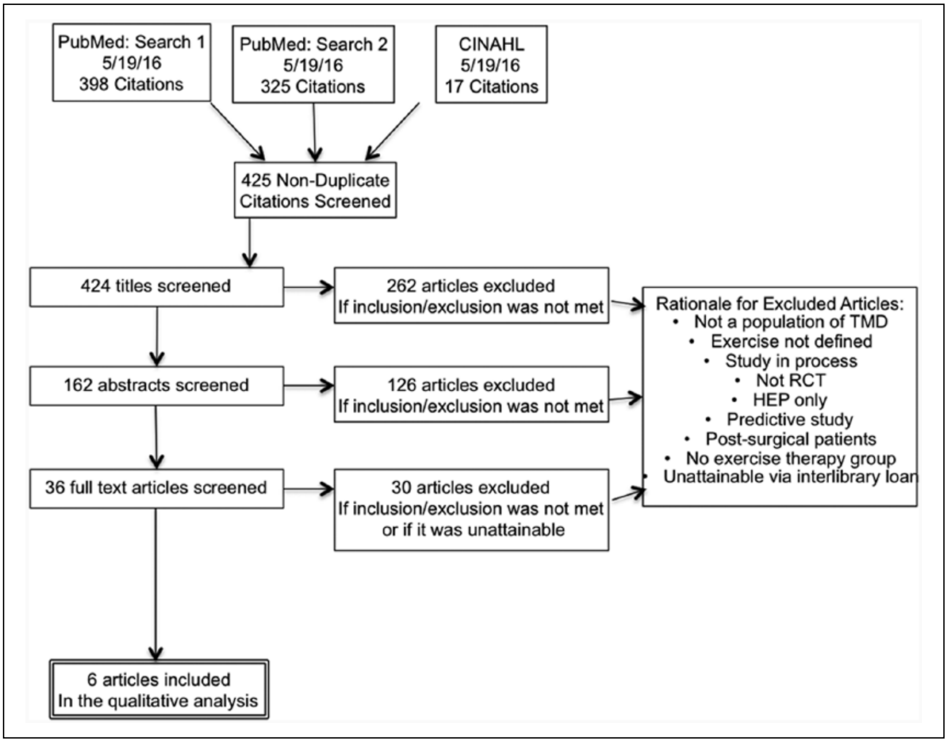

Figure 1. PRISMA flow diagram for inclusion.
HEP: home exercise program; RCT: randomized controlled trial; TMD: temporomandibular joint dysfunction.

exclusion. Kappa statistic was used to calculate the inter-rater agreement for the risk of bias tool and inclusion screening between examiners.

Eligibility

Articles were included if they met the following inclusion criteria: Randomized controlled trials study design; study participants were diagnosed with temporomandibular joint dysfunction and could not be post-surgical; an exercise intervention must be compared with another type of treatment or placebo and could not be exclusively a home exercise program; outcome report on at least one measure of pain and/or disability.

Data extraction

Data and results from the included articles were extracted using a standardized form that documented characteristics of the participants, diagnosis, interventions, follow-up periods, outcome measures, exercise intervention (prescription/dosage and adherence), and reported results.

Exercise prescription characteristics. The standardized definition of therapeutic exercise was utilized for this study.[11] Specific intervention characteristics of included studies were identified a priori by the research team. Characteristics had to contain elements associated with exercise types including: Program approach (e.g. prescriptive or pragmatic style), method and type of exercise delivery, and dosage (i.e. intensity, repetitions, sets, and/or load/resistance of the exercise prescription).

For the purpose of data synthesis, the research team characterized exercise therapy groups based on consensus and review of prior exercise therapy research. The exercise therapy categories included: (1) mobility, (2) motor control (direct or indirect),

(3) postural education, (4) mixed approach. The mobility category consisted of exercises intended to increase mobility of the temporomandibular joint and/or muscles of the jaw. This included interventions such as sustained stretched position of the jaw, controlled movements of the mandible, contraction–relaxation techniques, joint mobilizations, and soft tissue mobilization/myofascial stretching (active or passive). The motor control category included exercises to promote joint or muscular control and coordination of the mandible. Interventions, such as controlled symmetrical mobility, muscle energy, isometric contraction, or controlled mobility exercises performed in front of a mirror or with self-palpation of the temporomandibular joint are examples of exercises within this group. The postural education category included therapeutic intervention programs that emphasized instruction for the resting jaw position and/or exercises that emphasized head/neck or upper trunk posture.[6] Lastly, the mixed approach category included therapeutic exercise interventions that fit in two or more of the categories stated above, or when type of exercise was not identified with a specific purpose by the original authors.

Adherence. Adherence to the exercise prescription was also captured and extracted when possible, owing to the potential influence on the study results. A variety of adherence measures were accepted, as no standardized measure currently exists.[12–13]

Self-reported and measured outcomes. Outcome assessments including both the assessment of self-report measures and performance measures were captured. Constructs of pain, function/disability for self-report, and performance outcomes of jaw mobility and/or strength were synthesized at reported time points.

Risk of bias appraisal tool

The internal validity of each article was reviewed and scored for methodological quality using the Cochrane Risk of Bias Tool.[14] Table 1 (available online) demonstrates the six assessment domains that were assessed by two independent reviewers for each included article. Discordance in assessment was resolved by discussion with a third reviewer. The Cochrane Collaboration Tool for Assessing Risk of Bias[14] does not formulate a comprehensive quality score, only a judgement of "low," "unclear," or "high" risk.

Data analysis

The primary analysis compared the overall efficacy of the exercise intervention to a placebo or to another intervention for pain, function, and mobility outcomes at similar time points. Mean differences or standardized mean differences with 95% confidence interval (CI) were calculated using Comprehensive Meta-Analysis, version 2.0. The I^2 statistic was utilized to determine the degree of heterogeneity, where the percentages quantified the magnitude of heterogeneity: 25% = low, 50% = medium, and 75% = high heterogeneity. Using this scale, if I^2 was <50%, a fixed effects model was used, and if the I^2 was >50%, a random effects model was used.[15]

When quantitative pooling was not performed, results were qualitatively synthesized, including analysis of effect size calculations when possible.[16] Effect size is the value used to demonstrate the strength of a targeted intervention.[17] Interpretation of effect size describes values as trivial (<0.2), small (⩾0.2 to <0.50), moderate (⩾0.50 to <0.80), or large (⩾0.80).[17] Effect sizes of short- and long-term temporomandibular joint dysfunction interventions were compared among the articles.

Results

Study selection and methodological quality

The search yielded 425 non-duplicate articles to be screened based on the title and abstract. A total of 37 relevant articles were identified for full text review, resulting in six studies meeting inclusion criteria (Figure 1). Reasons for exclusion of full-text articles can be found in Appendix 2 (available online). The risk of bias for each included article

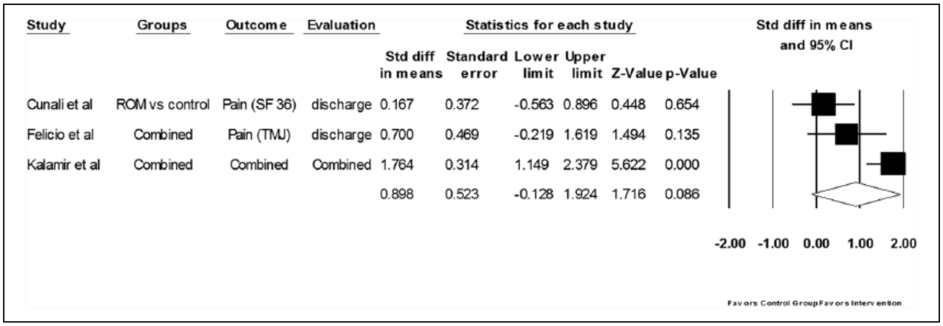

Figure 2. Meta-Analysis of Group Interventions on temporomandibular joint dysfunction pain outcome measures: Fixed effects model.

was completed and identified as low risk, high risk, or unclear (Table 1, available online) with excellent agreement by the research team for all items.

Study characteristics and outcome assessments

Data extraction on study characteristics and exercise therapy and dosage was completed on the included studies[18–23] with details provided in Table 2 (available online). Included articles consisted of 419 participants from ages 13 to 75 years old, where 84.7% were female. Significant variability in the patient population for individual articles was not found; however, patient population was variable across the included studies in terms of mean age, mean duration of symptoms, specific temporomandibular joint dysfunction, and additional diagnoses.

Four studies[19–22] randomized participants into two groups comparing an exercise therapy group to a control group, while the other two studies[18,23] randomized participants into more than two groups, comparing two different exercise intervention groups and a control. Effects found for participants without temporomandibular joint pain were not of interest in this review and therefore, the asymptomatic control group in the study by De Felicio et al.[23] was excluded from meta-analysis.

Three articles[18–20] assessed short-term follow-up periods, each including a measurement halfway between baseline and discharge. Time point of assessments varied between 10 minutes after treatment,[21] four weeks,[20] 17 weeks,[22–23] and 52 weeks.[18–19] Specific outcome measure tools varied depending on the domains with which the authors of each study sought to report (Table 1, available online). Although between-group comparisons were performed on pain in five studies,[18–20,22–23] function/disability in three studies,[19–20,22] and mobility in four studies,[18–21,23] two complete studies[20–21] and pain values for the third study[19] were excluded from the meta-analysis. This was after attempting to contact authors to obtain additional data required for statistical analysis. Details of included studies and effect size calculations are found in Tables 2–4 (available online).

Effect of exercise therapy on pain

All of the studies that included self-reported pain outcomes were pooled, this included pain measures at rest and with movement. When more than one measure was used for motion it was labeled as "combined," (Figure 2) from outcome measure on the SF36: pain,[22] temporomandibular joint pain,[23] and a report of opening, closing, and resting pain.[18] The results from 152 total participants demonstrated an Standard Differences in Means (SMD) of 0.824 with a 95% CI (Figure 2) indicating favor towards the intervention group. The study utilizing the SF36: pain[22] demonstrated no difference between groups. The study using temporomandibular joint pain[23] as the pain scale demonstrated no difference between the occlusal splint intervention group and control, although

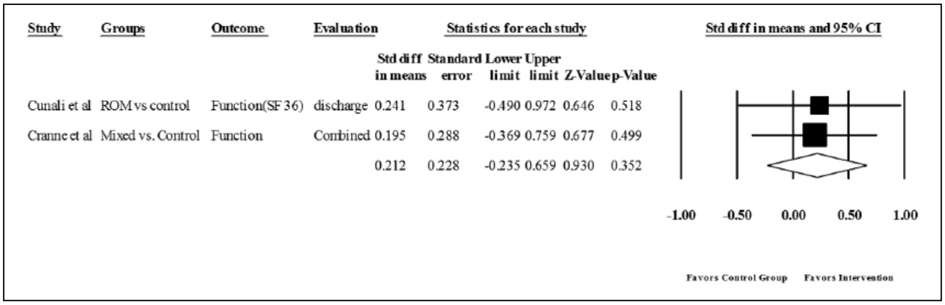

Figure 3. Meta-Analysis of Group Interventions on temporomandibular joint dysfunction functional outcome measures: Fixed effects model.

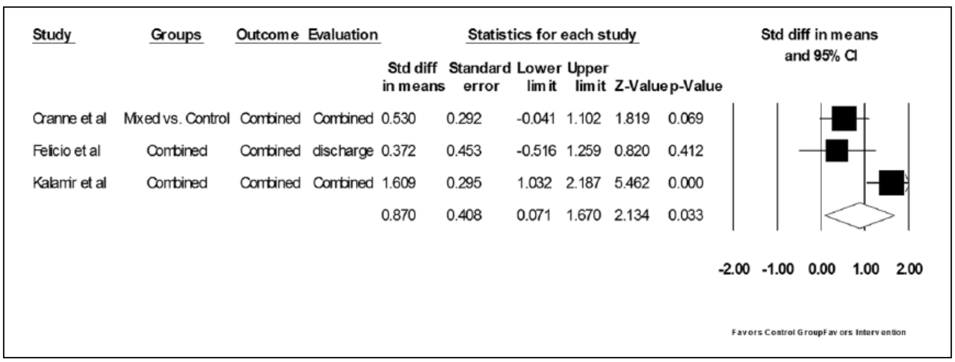

Figure 4. Meta-Analysis of Group Interventions on temporomandibular joint dysfunction range of motion measures: Fixed effects model.

favor towards the mixed approach intervention group was demonstrated over the control ($p=0.011$). The study with the combined pain scale[18] favored both the mixed exercise approach and mobility exercise intervention groups over the comparative controls.

Effect of exercise therapy effects on function

All of the studies that included self-reported functional outcomes were pooled (Figure 3) and measures included were the SF36: Functional Capacity (FC)[22] and the Mandibular Function Impairment Questionnaire.[18] The results from 78 total participants demonstrated an SMD of 0.212 with a 95% CI and $p=0.352$ (Figure 3). Although there was a small favor towards the intervention groups; the pooled results were statistically insignificant regarding function between intervention and control groups between all exercise groups.

Effect of exercise therapy effects on range of motion

All of the studies that included measurements of jaw mobility were pooled and labeled as “combined” (Figure 4), which included scales measuring maximal mouth opening[18–19] and a combination of temporomandibular joint range of motion for maximal mouth opening, left lateral excursion, right lateral excursion, and protrusion.[23] The results from 172 total participants demonstrated an SMD of 0.820 with a 95% CI (Figure 4) indicating favor towards the intervention group. Significant difference was demonstrated through assessment of maximal mouth opening[18–19] favoring the mixed approach and mobility groups and was illustrated with the pooled data ($p = 0.018$).

Exercise dosage

The inconsistency regarding dosage parameters is found in Table 2 (available online). The authors reported treatments one or two times each week[19,23] at a range of one to four times per day.[20,22] Treatment sessions ranged from 10 to 45 minutes.[18,21,23] Sets and repetitions also varied significantly. One study[21] reported exercise sets as time increments of 10 minutes, while other studies[20,22] gave a specific number of sets ranging from five to 10. Repetitions were reported at two to three,[20] five,[22] or ten.[20] In studies aiming to increase Range of Motion (ROM), the duration of holds ranged from 10 to 30 seconds.[20,23]

Adherence reporting

In general, the study methods for monitoring patient compliance/adherence were often ill reported. Specifically, within the six studies, the authors of four studies[18,20,21,23] did not report any method of tracking patient compliance over the duration of the study. Craane et al.[19] reported and recognized a major limitation of their randomized control trial was the lack of specific measurement for tracking compliance of the patients in performing a home exercise program. Cunali et al.[22] were the only authors to report patient adherence, in which subjects were required to keep a sleep logbook to record whether they completed the therapy described. The study did not provide data from the sleep logbook; therefore, no analysis could be completed on adherence.

Discussion

The main findings identified in the results of this systematic review and meta-analysis identify mobility and mixed exercise therapy approaches to appear to be the most common exercise approaches utilized for temporomandibular joint dysfunction. Exercise therapy and the associated dosage, within the included studies, demonstrated a moderate short-term and varying long-term effects in reduction of pain and improvement of range of motion of the patients with temporomandibular joint dysfunction. Interestingly, the meta-analysis identified that the current exercise therapy approaches used for patients with temporomandibular joint dysfunction did not significantly improve functional outcomes. Regardless of the reported outcome measures, there was significant variability found between studies regarding most effective dosage parameters and patient adherence measures, all of which is consistent with previous literature.[4–6]

Pain, mobility, and functional outcome measures were the most commonly reported within the included studies. Both mobility and mixed exercise therapy approaches were beneficial for pain reduction when compared with a control group. Reported types of exercises that help to reduce self-reports of pain include: Mobility-type exercises that utilized passive pressure to intra-oral muscles during active stretching;[18] mixed approach intervention incorporating motor control and postural education;[23] mixed approach intervention that included mobility, postural education, and patient education on self-care and a home exercise program.[18] The use of an occlusal splint and mobility exercises that incorporate the contract–relaxation technique for active stretching of the jaw did not provide significant changes in pain.[22–23]

Although slight improvements in functional outcomes were reported and effect sizes within the intervention groups were moderate, the meta-analysis resultantly identified that exercise therapies do not have a significant impact on improving functional outcomes for patients with temporomandibular joint dysfunction. Mobility exercises exhibit the greatest influence when addressing the construct of function, although this was statistically insignificant. It is important to note that the mobility group of the one study[22] was compared with a group receiving cervical exercises as the control. This is important because exercise therapies addressing head and neck posture were shown to increase mobility of the jaw and reduce pain in the study by Armijo-Olivo et al.[4]

In regards to range of motion improvement in temporomandibular joint dysfunction, some benefit is noted with mobility exercises therapy. Mobility exercise therapy activities may include passive pressure to intra-oral muscles during active stretching and with a mixed approach consisting of mobility, postural education, and patient education on self-care and a home exercise program.[19,23] The analysis suggests that treatments consisting of intra-oral myofascial therapy techniques with controlled active and passive opening in addition to stretching techniques, are beneficial over rest or rest with patient education for improving jaw mobility. However, a noticeable discrepancy was found among the efficacy of the interventions from these studies, demonstrating varying effects and reported statistical significance.[19,23] The discrepancy identifies a need for further studies capturing patient adherence and strict treatment parameters to determine the effects these variables have on patient outcomes.

Along with previous literature,[4–6] data extracted from this study revealed that each included article utilized a wide variety of exercises, demonstrating that no standard has been established with regards to interventions in this patient population. When comparing our findings to the meta-analysis by Armijo-Olivo et al., it is notable that there is only one study in common owing to the difference in criteria. Interestingly, all of the included studies in this article were categorized as mobility[18,20–22] or a mixed approach.[18,19,23] None of the studies utilized a motor control, postural education, or strengthening approach in isolation. It is important to note that interventions used across studies often were similar, but used to measure different constructs (pain, disability, or mobility). Only values for the effect of what the individual study was examining were used, even though there may be value in another construct not assessed by the authors. Another barrier to fully capturing the effectiveness of interventions was that not all studies reported means and standard deviations; therefore, we could not analyze the data for those studies.[20,21]

A secondary aim of this study was to examine the exercise prescription, specifically examining the type of exercise and dosage within the included studies. Although similar exercises were grouped by type, a common dosing pattern was not apparent. None of the studies provided evidence in dosage parameters for patients with temporomandibular joint dysfunction. This lack of consistency regarding dosage parameters is agreeable with previous literature[4–6] and suggests the essential need for further research on what parameters are appropriate for specific exercise therapies in patients with temporomandibular joint dysfunction. Although the dosage of exercise therapy was variable, studies demonstrating a larger effect on reducing pain reports had participants perform exercises once or twice per week and displayed significant improvements in pain,[18,23] while results were insignificant when participants performed exercises twice per day.[22] This may suggest that pain reduction may benefit from less aggressive frequencies of treatment, such as once or twice per week rather than daily.

The information found in this review had similar findings to previous literature with regards to exercise therapy effectiveness on various pain, function/disability, and mobility outcome measures.[4–6] A mixed approach to interventions embraces multidimensional methods for treatment of patients with temporomandibular joint dysfunction. This may include emphasis on patient education and a home exercise regimen in conjunction with specific exercises for the temporomandibular joint. None of the prior reviews included adherence and dosage as parameters of investigation, although Armijo-Olivo et al. noted that testing adherence in studies was an issue.[4] As with the previous evidence, this current systematic review and meta-analysis found the need for further research to determine treatment superiority in patients with temporomandibular joint dysfunction.

Limitations

The exclusion criteria of this study may have led to omitting additional studies reporting exercise dosage. This review did not include studies that examined patients with Myofascial Pain Syndrome if they were not diagnosed with a temporomandibular joint dysfunction disorder. Additionally, there were only a small number of included studies, with 419 patient representatives within this analysis. Several studies were included despite risk of bias according to the Cochrane Risk of Bias Tool.[14] Caution should be made when applying findings to clinical practice owing to small sample sizes within trials, limited reporting of data, and variability in treatment and outcome measures used. Data extraction was altered throughout the systematic process because of the gap in literature surrounding this topic and the defined exclusion criteria. Lack of data reporting in two of the six studies prevented us from including their findings for treatment effects in our analysis.

Clinical importance

This study has provided a synthesis of randomized controlled studies that included exercise therapy treatment for patients diagnosed with all types of confirmed temporomandibular joint dysfunction conditions. Exercise therapy does not appear be a significant direct improvement with oral functional improvements despite improvements of range of motion. The improvements of range of motion came from the exercise therapy emphasizing mobility interventions and a mixed multidimensional treatment program. Although the mixed exercise therapy approach twice weekly appears to be the most effective treatment method for pain outcomes. This review indicates exercise therapy had moderate treatment effects in the short-term and varying amounts of long-term treatment effects in patients with temporomandibular joint dysfunction. Results were drawn from minimal evidence; therefore, conclusions should be taken with caution. Future studies should be designed with descriptions of given exercise therapies, to identify appropriate exercise dosage, short- and long-term benefits, track patient adherence to therapy, and determine how these each impact patient outcomes.

Clinical message

- Patients with temporomandibular joint dysfunction have less pain and better jaw range of motion after exercise therapy targeting mobility or a mixed, multidimensional approach.
- The evidence cannot determine the most appropriate type, intensity, and duration of therapy; it suggests greater intensity may exacerbate pain.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Photobiomodulation and myofascial temporomandibular disorder: Systematic review and meta-analysis followed by cost-effectiveness analysis

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Abstract

Background: Photobiomodulation (PBM) is a non-invasive and non-pharmacological treatment, which, has shown beneficial results in the treatment of temporomandibular disorders (TMD) related pain. This systematic review and meta-analysis study aimed to evaluate the efficacy of photobiomodulation in the treatment of myofascial pain associated with (TMD by analyzing randomized clinical trials published from 2007 to February 2019. The secondary objective of the study was to perform a cost-effectiveness analysis of TMD treatment with photobiomodulation in patients with myofascial pain.

Material and Methods: International databases were used: Pubmed, Medline and Web of Science; the initial search raised 316 papers, and only 17 papers met the inclusion criteria for the systematic review (SR). Of these, only 04 papers met the inclusion criteria for meta-analysis: VAS data represented by numerical scores and placebo control group.

Results: As for the wavelength, the most used value was 780nm (followed by 830nm. The most used treatment time was 4 offered treatments for 4 weeks; followed by 10 sessions. Regarding periodicity, 9 studies used 2 times a week. The meta-analysis showed that laser-treated groups had painful symptoms improvement that was superior to the control group (mean difference 1.49;95% CI = -1.67; -1.32). Laser therapy showed a cost-effectiveness of $1,464.28 by controlled pain intensity and placebo showed $2,866.20 by controlled pain intensity.

Conclusions: The studies were considered to have moderate quality of evidence. Laser-treated groups had painful symptoms improvement that was superior to the control group and photobiomodulation was more cost-effective than placebo in patients with TMD and myofascial pain.

Key words: *Temporomandibular disorder, Myofascial pain, Photobiomodulation, Placebo, Cost-effectiveness.*

Introduction

Temporomandibular disorder (TMD) is a term used to define clinical signs and symptoms affecting the masticatory muscles, the temporomandibular joint (TMJ) and associated structures (1-5). Among the most frequent signs and symptoms are masticatory muscle tenderness, pain in one or both TMJs, limited jaw movements, joint noise (5-7) and headache (5,8,9). TMD signs and symptoms are found at all ages; however, the prevalence of this disorder, considered low in children, increases with age in adolescents and young adults (10,11). Such disorders are a major cause of non-dental pain in the orofacial region, with 40% to 75% of nonpatient adult populations displaying at least one sign, and approximately 33% reporting at least one symptom of TMJ dysfunction (2). Among TMDs, the most common is myofascial pain, which causes pain and limited function, especially in chewing (4). Several resources, mainly for pain control, have been proposed for treatment such as occlusal splint, acupuncture, kinesiotherapy, massage therapy, postural training, psychotherapy, joint mobilizations, drug therapy, and laser therapy (12-13).

Low-level laser therapy (LLLT) or photobiomodulation (PBM) is a non-invasive and non-pharmacological treatment, which, according to several studies, has shown beneficial results in the treatment of TMD-related pain. (3-6,13-21).

The therapeutic effects of LLLT on TMD include inflammatory modulator and analgesic effects (4,5,7,21,22). Low-level lasers have demonstrated an ability to assist in the symptomatic treatment of pain, promoting a considerable degree of comfort to patients soon after its application. A major advantage of laser therapy for TMD is that it is a non-invasive, low-cost therapy and is currently widely used in dental practice, reducing the need for surgery or the use of drugs for pain relief and tissue regeneration. The use of laser therapy in patients with TMD has demonstrated pain relief minutes after application, promoting significant well-being. However, it is an adjunctive pain relief treatment due to the analgesic action of the laser which allows patients to resume their activities, providing them with greater convenience and better quality of life (4,5,21,22).

The main objective of this systematic review and meta-analysis was to assess the efficacy of photobiomodulation in the treatment of myofascial TMD by analyzing randomized clinical studies published within the period from 2007 to February 2019. The secondary objective was to conduct a cost-effectiveness (CE) study based on the results of the meta-analysis.

Material and Methods

In order to maintain the methodological rigor of the systematic review and meta-analysis, the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyzes) guide was used to aid the process, offering guidance to improve the quality of data reporting (23). The systematic review protocol was registered in PROSPERO CRD42019131016.

-Search Strategy

Search strategy was conducted with the assistance of an expert medical librarian. A systematic search of the literature was conducted using sources, PubMed, Web of Science and MEDLINE, between 2007 and February 2019. The search was restricted to papers written in English and limited to randomized clinical studies whose treated patients had a diagnosis of temporomandibular disorder with myofascial pain.

-Selection of studies

An initial research using the keywords ("temporomandibular" OR "temporomandibular disorder" OR "temporomandibular joint" AND "temporomandibular joint" OR "low intensity laser therapy" OR "laser therapy" OR "photobiomodulation" OR "phototherapy" AND "myofascial pain"), in the databases (Pubmed, Medline and Web of Science) resulted in 316 studies. After reading the title and abstract, 17 papers that met the inclusion criteria were selected, as shown in Figure 1. The analysis was carried out by 2 trained reviewers and only randomized clinical studies were included, as they have higher level of evidence.

-Inclusion Criteria

First stage, two reviewers independently screened all the titles and abstracts identified by the electronic searches to identify the potentially relevant articles to be retrieved. Second stage, full-text copies of these studies were assessed by the same two reviewers for inclusion using the eligibility criteria according to PICO strategy. The research question was established based on the structured PICO, in the systematic review is question format was as follows: "What is the effectiveness of photobiomodulation in the treatment of TMD in patients with myofascial pain when compared to placebo?"

P (population): Patient Diagnosis of temporomandibular disorder with myofascial pain

I (Intervention): Laser therapy

C (Comparison): Placebo

O (Outcomes): Pain (VAS)

In order to obtain homogeneity among the selected studies for the meta-analysis to be carried out, only the works that used the VAS scale (Visual Analogue Scale) were selected to evaluate the interference result. For the meta-analysis, only studies that used the simulated placebo in the control group and that showed numerically arranged data were included.

-Data Extraction

A data extraction form was designed to enable data extraction relating to the study author and year of publication, country where the study was conducted, number of subjects, type of laser, radiant exposure (J/cm^2),

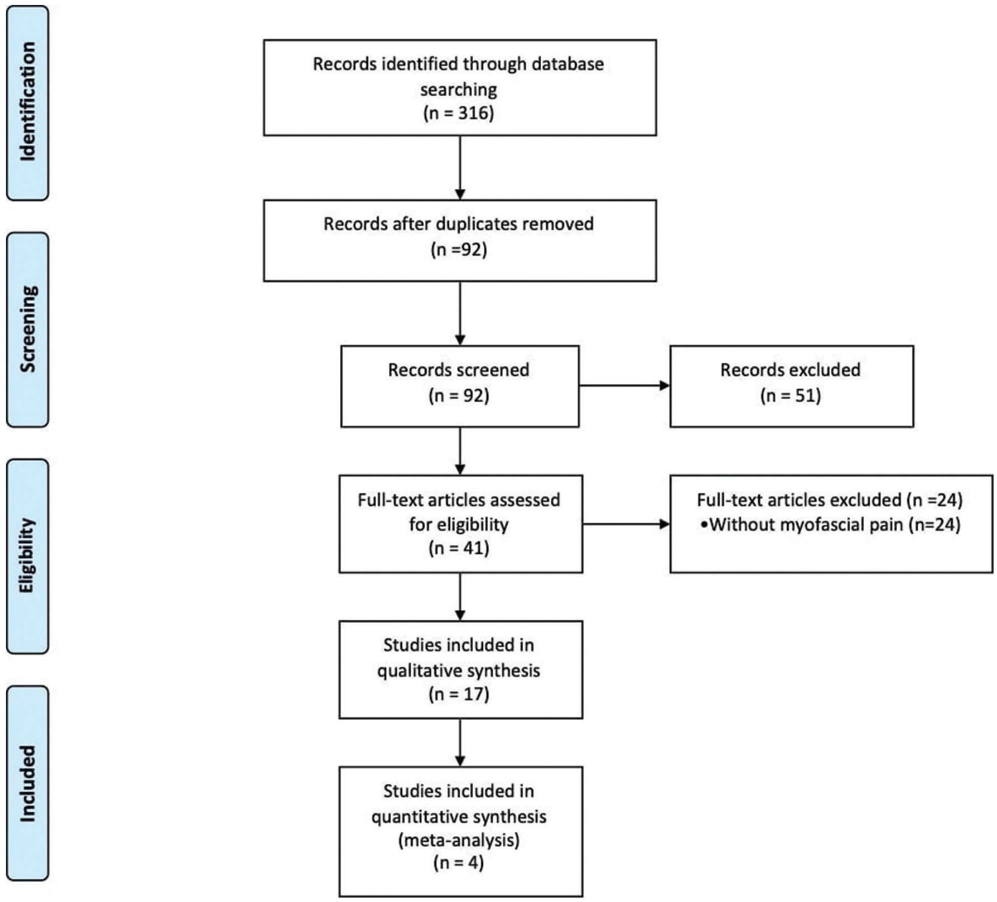

Fig. 1: PRISMA flow chart.

wavelength (nm), power (mW), treatment duration and frequency. Data extraction was performed by 1 reviewer and checked for accuracy by a second reviewer.

-Assessment of Risk of Bias

The risk of bias was assessed using the revised Cochrane risk of bias tool (RoB 2.0) in accordance with the study design of the included trials. Risk of bias assessment of the included studies was undertaken by one reviewer and checked for agreement by a second reviewer.

-Quality of Evidence

The quality of evidence for the primary outcomes was assessed using GRADE criteria. Evidence was classified as either very low, low, moderate, or high quality determined by risk of bias, inconsistency of results across studies, indirectness of available evidence, imprecision of results, and publication bias.

-Cost-Effectiveness Analysis

Cost-effectiveness establishes whether a treatment should be implemented as a therapeutic measure, being calculated by the difference between the cost of two interventions proposed as treatment divided by the difference between its consequences (effectiveness) (24).

-Cost Analysis

The cost of the visit (laser application session) was based on data presented by healthcare operators in Brazil and the treatment considered hospital costs in Brazil, following information from TUSS (Unified Terminology for Supplementary Health - Medical Procedures), with code and description: 31602215- LASER - PER SESSION (http://www.ans.gov.br/images/stories/Legislacao/in/anexo_in34_dides.pdf). An average of 2 sessions per week was considered, with 6 weeks of laser therapy, according to what was observed in the protocol by Sobral *et al*. (25).

In this research study, only direct medical costs were used, and the price of all materials used in the procedures was considered for calculation.

-Effectiveness Analysis

Treatment effectiveness in the systematic review followed by meta-analysis was measured by pain assessment using VAS data before and after treatment in the photobiomodulation and placebo groups.

-Data Analysis

The meta-analysis of relative risk was carried out based on the selected dichotomous results. Heterogeneity between the studies was calculated using I2 statistics and the analysis used the fixed effects model in this study. The results were described with the respective 95% confidence interval (95% CI). Calculations were performed using the R software (The R Foundation for Statistical Computing, Austria). For all analyses, the level of significance was established as α= 0.05.

Results

•Systematic Review

-Characteristics of Included Studies

Papers were arranged in a table (Table 1), mentioning authors, country of the authors, year of publication, the number of patients who entered the study, the type of laser device, energy density, and the time and periodicity of treatment.

Table 1: Papers included in Systematic Review.

Authors	**Country**	**Year**	**No. of patients**	**Laser type**	**Radiant Exposure (J/cm²)**	**Wave-length (nm)**	**Power (mW)**	**Laser therapy time**	**Periodicity**
Magri LV *et al.* 2018 (26)	Brazil	2018	41	GaAlAs	Masseter=5 Temporal=7.5	780	Masseter= 20 Temporal= 30	4 weeks = 8 sessions	twice a week
Borges, RMM *et al.* 2018 (27)	Brazil	2018	44	AlGaAs	8 60 105	830	30	3.5 weeks = 10 sessions	3 times a week
Manfredini D *et al.* 2017 (28)	Italy	2018	30	Lsl-GaAs	---------	808 905	1.1 25	3 weeks = 9 sessions	3 times a week
Magri LV *et al.* 2017(29)	Brazil	2017	91	GaAlAs	Masseter and Temporal=5 TMJ = 7.5	780	20 30	8 weeks = 16 sessions	twice a week
De Carli BM *et al.* 2016 (30)	Brazil	2016	---------	Lsl-GaAs	18	904	---------	---------	---------
Demirkol N *et al.* 2015 (31)	Turkey	2015	30	Nd:YAG	8	1.064	250	10 days	Once a day
Rodrigues JH *et al.* 2015 (32)	Brazil	2015	10	---------	---------	780	10 70	---------	---------
Leal de Godoy CH *et al.* 2015 (33)	Brazil	2015	9	GaAlAs	33,5	786.94	50	6 weeks = 12 sessions	twice a week
de Moraes Maia ML *et al.* 2014 (4)	Brazil	2014	21	GaAlAs	70	808	100	4 weeks = 8 sessions	twice a week
Manca A *et al.* 2014 (34)	Italy	2014	60	---------	---------	---------	30	2 weeks = 10 sessions	5 times a week
Uemoto L *et al.* 2013 (35)	Brazil	2013	21	---------	Right Masseter = 4 Left Masseter = 8	795	80	73 hours	48 to 72 hours
Ferreira LA *et al.* 2013 (36)	Brazil	2013	38	GaAlAs	112,5	780	50	4 weeks = 8 sessions	twice a week
Venezian GC *et al.* 2010 (13)	Brazil	2010	48	GaAlAs	25 60	780	50 60	4 weeks = 8 sessions	twice a week
Öz S *et al.* 2010 (37)	Turkey	2010	40	Laser Diode	3	820	300	5 weeks = 10 sessions	twice a week
Katsoulis *et al.* 2010 (38)	Switzerland	2010	11	---------	40 60	690	40	3 weeks = 6 sessions	twice a week
Carrasco TG *et al.* 2008 (6)	Brazil	2009	60	GaAlAs	25 60 105	780	50 60 70	4 weeks = 8 sessions	twice a week
Fikácková H *et al.* 2007 (14)	Czech Republic	2007	61	GaAlAs	0,1 10 15	830	400	5 weeks = 10 sessions	---------

As observed in the studies included in this work, there is no consensus regarding radiant exposure. Out of the 17 studies, 2 used: 5J/cm² (masseter) and 7.5 J/cm² (temporal) and 2 other studies, 25 J/cm² and 60 J/cm². As for the wavelength, the most used value was 780nm (35.29% - 6 studies), followed by 830nm (11.76% - 2 studies).

Based on the studies analyzed, the most used treatment time was 4 offered treatments for 4 weeks (4 studies); followed by 10 sessions, 3 studies. Regarding periodicity, 9 studies used 2 times a week.

-Systematic Review - Risk of Bias

When assessing the risk of bias in the studies, Table 2 and Figure 2 demonstrate the risk of bias in each study individually, for each domain considered in the risk assessment, using RoB 2.0 tool of the Cochrane collaboration.

•Meta-Analysis

The initial search resulted in 316 randomized clinical trials published from 2007 to February 2019, from which 17 papers were found and selected after evaluation by 2 reviewers, 4 of which met the inclusion criteria for meta-analysis: VAS data represented in numerical score and placebo control group.

-Quality of Evidence - GRADE

The papers included in this study underwent assessment as to the quality of evidence. Thus, according to the GRADE (Grading of Recommendations Assessment, Developing and Evaluation), Table 3 shows the quality of evidence for each study included.

It was observed that only 2 studies had a high degree of evidence quality, 1 had a moderate degree of evidence quality, and the other study had a low level of evidence quality. The studies were considered to have moderate and low quality of evidence because randomization and blinding were not well described and ensured in the methodology.

-Effect of Low-Level Laser Therapy on TMD

In total, with the 4 studies included in this meta-analysis Magri *et al*. (26), Demirkol *et al*. (31), de Moraes Maia *et al*. (4) and Magri et. al (29), this study evaluated 143 patients. According to Figure 3, we can see that 73 patients were in the laser group, while 70 were in the control group (placebo). These patients were further divided in terms of event, and effectiveness was measured by means of the difference in the absolute mean of VAS scores before and after treatment (1.49).

Table 2: Risk of individual bias in the seventeen studies selected for the systematic review, for each domain of risk assessment of bias in randomized clinical trials using the Cochrane collaboration tool.

Generation of the random sequence	Assignment concealment	Blinding of subjects and professionals	Blinding of outcome evaluators	Incomplete outcomes (losses)	Selective outcome report	Other biases
Low	Low	Low	Low	Low	Low	Low
High	High	High	High	Uncertain	Low	Low
Uncertain	High	High	High	Uncertain	Low	Low
Low	Uncertain	Uncertain	Uncertain	Low	Low	Low
Uncertain	Uncertain	Uncertain	Uncertain	Low	Low	Low
Low	Low	Low	Low	Uncertain	Low	Low
Low	Low	Low	Low	Low	Low	Low
Low	Low	Low	Low	Low	Low	Low
Low	Uncertain	Uncertain	Uncertain	Low	Low	Low
Uncertain	High	High	High	Low	Low	Low
Low	Low	Low	Low	Low	Low	Low
Low	Uncertain	High	High	Low	Low	Low
High	High	High	High	Low	Low	Low
Uncertain	High	High	High	Uncertain	Low	Low
Uncertain	High	High	High	Uncertain	Low	Low
Low	Low	Low	Low	Low	Low	Low
Low	Low	Low	Low	Uncertain	Low	Low

Fig. 2: Risk of individual bias.

Table 3: Evaluation of the Quality of Evidence from Studies.

Study / Author	Quality of Evidence
Effectiveness of low-level laser therapy on pain intensity, pressure pain threshold, and SF-MPQ indexes of women with myofascial pain (Magri, 2017)	● ● ● ● high
Effectiveness of occlusal splints and low-level laser therapy on myofascial pain (Demirkol, 2015)	● ● ○ ○ low
Evaluation of low-level laser therapy effectiveness on the pain and masticatory performance of patients with myofascial pain (De Morais Maia, 2014)	● ● ● ○ moderate
Non-specific effects and clusters of women with painful TMD responders and non-responders to LLLT: double-blind randomized clinical trial. (Magri, 2018)	● ● ● ● high

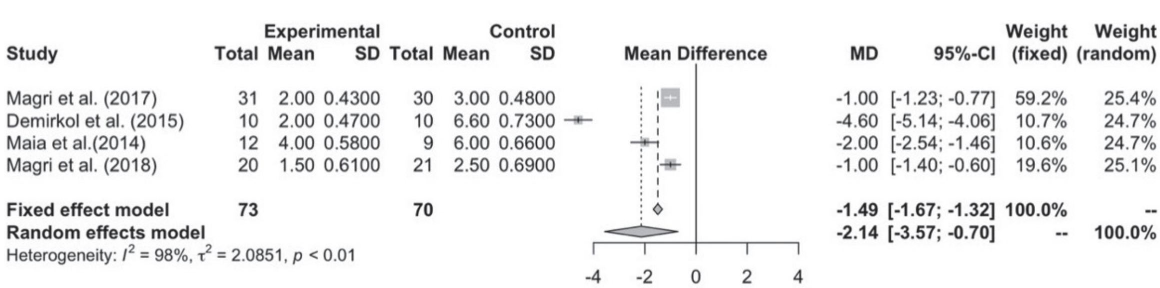

Fig. 3: Forest Plot with Data from Meta-Analysis Studies.

For this analysis, pain was considered as the outcome measure, being assessed by the visual analogue scale. The 4 studies were grouped for meta-analysis. The forest plot (Fig. 3) describes the weighted meta-analysis regarding pain intensity in patients with TMD. Significant heterogeneity was observed among the studies (I2 = 98%; *p* <0.01) and a statistically significant difference was observed between the laser-treated group and the placebo group. The total mean difference was 1.49 (95% CI = -1.67; -1.32). The meta-analysis showed that laser-treated groups had painful symptoms improvement that was superior to the control group.

As for the mean difference analyzed separately for each study, the difference ranged from -1.00 to -4.60 on the pain scale. That is, in all studies it was possible to notice that the laser group shows a superior and statistically significant improvement in painful symptoms, which shows treatment effectiveness for cases of muscle pain in patients with TMD.

•Cost-Effectiveness

For the cost-effectiveness analysis, the value of 1.49 was considered as effectiveness, which represents the difference in the absolute mean of VAS scores before and after treatment (1.49) and the costs were calculated for a total of 12 sessions.

Table 4 describes the costs per patient and also per group within the sample, with the total cost of 12 sessions.

Table 4: Description of treatment costs in the laser and control groups.

	Laser group (GL)	Control Group (GC)
Cost of 12 sessions* Cycle per patient	\$ 506.40	\$ 506.40
Cost of 12 sessions* Total N cycle	\$ 36.96.20 n=73	\$ 35,448.00 n=70

The incremental cost of the Pain outcome in this study is \$992.75 per controlled pain intensity. The cost-effectiveness ratio for clinical treatment in the laser and placebo groups was \$1,464.28 and \$2,866.20 for controlled pain, respectively. The laser group being more cost-effective than the placebo group.

Discussion

The analyzed papers in RS indicate that low-level laser has been increasingly used to treat patients with myofascial TMD due to its analgesic, regenerative and anti-inflammatory effects and also due to the conservative characteristic of treatment. The survey also showed that no agreement has yet been reached regarding the parameters used in the treatments and, therefore, we do not have a defined protocol for the treatment of myofascial TMD. This can make it difficult for the treatment to be standardized in public healthcare.

In addition, an aspect that made the analysis of the protocols used quite difficult is precisely because the authors did not provide all parameters for laser application. This occurred in 7 studies included in this study.

Of the 17 papers evaluated, we found a twice a week periodicity for laser therapy time in 10 studies, the minimum was 73 hours, and the maximum was 12 weeks. This study used the same periodicity and duration of treatment as the study by Leal de Godoy *et al*. (33).

The minimum parameter of 3 J/cm^2 has managed to show satisfactory results in improving pain and also in opening the mouth of patients with myofascial TMD (37).

According to what was possible to observe in this meta-analysis, all the studies analyzed showed that the laser-treated group had statistically superior improvement in painful symptoms when compared to the placebo group.

Ahrari *et al*. (18) conducted a randomized, double-blind clinical trial with 20 female patients who had myogenic TMD. The patients were divided into two groups, the laser group and placebo. As a result, it was observed that there was a significant reduction in pain symptoms in the laser group and a significant increase in the mouth opening parameter (p<0.05). Statistically significant improvement was not seen in the placebo group. Thus, the authors concluded that LLLT can provide significant improvements in the level of pain and mouth opening in patients with myogenic TMD. The relative risk made by the proportion of all studies included in the meta-analysis was 1.49, using the fixed model, since the studies evaluated the same effect in different samples, through VAS. When assessing quality of evidence in the studies, only one study showed low quality, two showed high quality and one showed moderate quality of evidence.

If we analyze the relative risk of each study, the works by Magri *et al*. (26,29) were the ones with the lowest relative risk, 1.00 and their weights in the analysis were 59.2% and 19.6%, being the highest weights in the study. The work by Demirkol *et al*. (31) showed the highest relative risk, 4.60 and its relative weight in the analysis was 10.7% when compared to the placebo group. But, for the relative risk, analyzing all the studies.

When the quality of the evidence from the studies was considered, the studies by Magri *et al*. (26,29) showed high quality of evidence and that of Demirkol *et al*. (31) showed a low level of quality of evidence.

Conclusions

According to what was observed in the studies analyzed through systematic review and meta-analysis, laser therapy is effective when compared to placebo and more cost-effective in the treatment of myofascial TMD.

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Author contribution

Ana Paula Taboada Sobral: conceptualization, methodology, data curation; formal analysis; writing- original draft, writing- review & editing; Sergio de Sousa Sobral: methodology, software, data curation; formal analysis; roles/writing-original draft; Thalita Molinos Campos: conceptualization, validation; roles/writing-original draft; Anna Carolina Ratto Tempestini Horliana: conceptualization, validation; roles/writing-original draft; Kristianne Porta Santos Fernandes: methodology, formal analysis, data curation, writing - review & editing; Sandra Kalil Bussadori: resources, methodology, software,writing - review & editing; Lara Jansiski Motta: conceptualization, methodology, data curation; formal analysis; writing- review & editing, supervision.

Conflict of Interest

The authors report no conflicts of interest related to this study. They did not receive any funding for this study.