

# A Systematic Review of the Effectiveness of Physical Therapy Interventions for Temporomandibular Disorders

**Background and Purpose.** The purpose of this qualitative systematic review was to assess the evidence concerning the effectiveness of physical therapy interventions in the management of temporomandibular disorders. **Methods.** A literature search of published and unpublished articles resulted in the retrieval of 36 potential articles. **Results.** Twelve studies met all selection criteria for inclusion in the review: 4 studies addressed the use of therapeutic exercise interventions, 2 studies examined the use of acupuncture, and 6 studies examined electrophysical modalities. Two studies provided evidence in support of postural exercises to reduce pain and to improve function and oral opening. One study provided evidence for the use of manual therapy in combination with active exercises to reduce pain and to improve oral opening. One study provided evidence in support of acupuncture to reduce pain when compared with no treatment; however, in another study no significant differences in pain outcomes were found between acupuncture and sham acupuncture. Significant improvements in oral opening were found with muscular awareness relaxation therapy, biofeedback training, and low-level laser therapy treatment. **Discussion and Conclusion.** Most of the studies included in this review were of very poor methodological quality; therefore, the findings should be interpreted with caution. [McNeely ML, Armijo Olivo S, Magee DJ. A systematic review of the effectiveness of physical therapy interventions for temporomandibular disorders. *Phys Ther.* 2006;86:710–725.]

**Key Words:** *Electrophysical modalities, Exercise, Manual therapy, Physical therapy, Systematic review, Temporomandibular joint disorders.*

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**T**emporomandibular disorders (TMDs), also referred to as craniomandibular disorders, consist of a group of pathologies affecting the masticatory muscles, the temporomandibular joint (TMJ), and related structures.<sup>1,2</sup> Temporomandibular disorder is considered a musculoskeletal disorder of the masticatory system that affects more than 25% of the general population.<sup>3</sup> Temporomandibular disorder is usually manifested by one or more of the following signs or symptoms: pain, joint sounds, limitation in jaw movement, muscle tenderness, and joint tenderness.<sup>4</sup> It also is commonly associated with other symptoms affecting the head and neck region such as headache, ear-related symptoms, and cervical spine disorders.<sup>3,5</sup> Patients with chronic TMD frequently report symptoms of depression, poor sleep quality, and low energy. Furthermore, chronic TMD has been found to interfere with normal social activity and interpersonal relationships and to negatively affect the ability to maintain employment.<sup>6</sup>

The American Academy of Craniomandibular Disorders and the Minnesota Dental Association have cited physical therapy as an important treatment.<sup>7</sup> Physical therapy is intended to relieve musculoskeletal pain, reduce inflammation, and restore oral motor function. Numerous physical therapy interventions are potentially effective in managing TMD, including electrophysical modalities, exercise, and manual therapy techniques. Electrophysical modalities include interventions such as ultrasound, microwave, laser, and transcutaneous electrical nerve stimulation (TENS). Physical therapy interventions often include therapeutic exercises for the masticatory or cervical spine muscles to improve strength (ie, the force-generating capacity of muscle) and mobility in the region.<sup>8</sup> Manual therapy techniques are commonly used to reduce pain and restore mobility. Oral exercise devices, such as the Therabite Jaw Motion Rehabilitation System,\* are mechanical aids that provide passive stretch to the TMJ to improve mandibular range of motion. Physical therapy interventions also may include, or focus on, associated impairments of the

craniocervical system such as poor posture, cervical muscle spasm, cervical pain, or referred pain from the cervical spine.<sup>8</sup> Acupuncture also was included as an intervention in this review because it is considered a specialty field within the scope of practice for many physical therapists working in countries such as Canada, the United Kingdom, and Australia.

Management of TMD, however, most often involves a multidisciplinary approach. Dentists, orthodontists, psychologists, physical therapists, and physicians work together to address the condition of the patient with TMD. Conservative treatment is considered to be the treatment of choice because the symptomatology of the condition often is improved by use of occlusal splints, physical therapy, medication, and orthodontic treatment.<sup>9</sup> Many reviews have been published on conservative treatments, often recommending a multidisciplinary treatment approach for TMD; however, research evidence supporting this approach is usually not provided.<sup>7,10-12</sup>

More recently, there has been an interest in the relative effectiveness of specific conservative interventions for TMD, and, as a result, a number of systematic reviews have been performed in the area.<sup>13-17</sup> One systematic review by Ernst and White,<sup>14</sup> published in 1999, examined the efficacy of acupuncture for TMD. Based on preliminary findings from only 3 trials in the area, the authors concluded that, although acupuncture may be a potentially effective intervention for TMD, more rigorous trials were needed to confirm this conclusion.<sup>14</sup> A meta-analysis, also published in 1999, examined the efficacy of electromyographic (EMG) biofeedback for TMD.<sup>13</sup> Based on their meta-analysis of 13 studies, the authors concluded that there was evidence to support the use of EMG biofeedback in the management of TMD. The conclusions of the meta-analysis, however, were based on data from controlled and uncontrolled trials, and the findings therefore should be interpreted with caution.

More recently, 2 separate systematic reviews have examined the effectiveness of stabilization splint therapy

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(2004)<sup>16</sup> and occlusal adjustment (2005)<sup>17</sup> in the management of TMD. Based on the findings of these 2 reviews, there is currently insufficient evidence to support or refute the use of stabilization splint therapy and no evidence to support occlusal adjustment in the management of TMD.

To date, the question of whether physical therapy interventions are effective in the management of TMD remains unanswered. Thus, the purpose of this systematic review was to evaluate the methodological quality of, and summarize the evidence from, randomized controlled trials (RCTs) that examined the effectiveness of physical therapy interventions in the management of TMD.

## Method

### *Criteria for Considering Studies for This Review*

Studies were considered eligible for inclusion in this review if they were RCTs comparing physical therapy intervention to a placebo intervention, controlled comparison intervention, or standard care (ie, treatment that normally is offered).<sup>18</sup> Studies with an additional treatment arm or combined intervention (eg, splint therapy) were included if the effect of the physical therapy intervention could be separately identified.

Inclusion in this review was restricted to trials with participants meeting the following criteria: (1) diagnosis of temporomandibular disorder, (2) adult subjects (>18 years of age), (3) musculoskeletal dysfunction, (4) pain impairment, (5) no previous surgery in the temporomandibular region, and (6) no other serious comorbid conditions (eg, fracture in region, cancer, rheumatic disease, neurological disease).

Studies were required to examine an intervention within the scope of physical therapist practice such as exercise, acupuncture, electrophysical modalities (eg, ultrasound, TENS), manual therapy, or a mechanical therapy device. The primary outcomes of interest included pain, range of motion, and oral function. Secondary outcomes of interest included EMG activity and patient satisfaction. Information was sought on complications (adverse events) resulting from the physical therapy intervention.

### *Search Strategy*

For this review, the literature was searched for published studies on physical therapy interventions for temporomandibular joint disorders. A literature search of studies was conducted according to the search strategy of Dickersin et al.<sup>19</sup> No restrictions were made regarding the language of publication. An extensive search of bibliographic databases included MEDLINE (1966–February week 4, 2005), EMBASE (1988–February week 4, 2005),

Cochrane Library and Best Evidence (1991–first quarter 2005), ISI Web of Science (1965–March 3, 2005), PubMed (1966–March 3, 2005), Lilacs (1982–March 3, 2005), EBM reviews–Cochrane Central Register of Controlled Trials (1991–first quarter 2005), and CINAHL (1982–February week 4, 2005). Key words and medical subject headings related to TMD and physical therapy were identified prior to initiating the search with the assistance of a librarian who specialized in health science databases. The key words included: “craniomandibular disorder(s),” “temporomandibular disorder(s),” “temporomandibular joint,” “orofacial pain,” “physical therapy,” “physiotherapy,” “exercise(s),” “rehabilitation,” and “therapy.” Two independent investigators screened the titles of publications found in the databases, and, if available, the abstract of the publication as well. If either investigator felt that any published article potentially met the inclusion criteria, or if there was inadequate information to make a decision, a copy of the article was obtained.

The next phase of the search strategy involved searching for unpublished studies and for studies potentially overlooked or absent from the databases. This involved hand searching the references of all retrieved articles for potential studies and hand searching selected journals (*Journal of Oral Rehabilitation*, *Journal of Orofacial and Maxillofacial Surgery*, *Journal of the American Dental Association*, *Cranio*, *Journal of Orofacial Pain*, and *Physical Therapy*). In order to locate unpublished research, we searched Web sites housing details of clinical trials, theses, or dissertations. Citation indexing was used to track referencing of key authors in the field, and local experts were contacted for further information.

A rating form was developed to determine eligibility of the retrieved papers (Appendix 1). Each criterion was graded on a yes/no basis (ie, the published paper had to provide enough information to adequately meet the criterion). In order for papers to be included in the review, the paper had to meet all criteria on the rating form. When discrepancies occurred between reviewers in the overall rating of an article, the rating forms were compared, the reasons for the discrepancies were identified, and a consensus was reached. All disagreements were resolved by consensus. Kappa statistics were calculated using SPSS version 12.0 software<sup>†</sup> to determine the level of agreement between raters on both trial inclusion and quality score. Based on the criteria described by Landis and Koch,<sup>20,21</sup> an agreement score above .61 was considered acceptable.

### *Quality Assessment*

Assessments of quality were completed independently by the 2 independent reviewers. Each study was evaluated

<sup>†</sup> SPSS Inc, 233 S Wacker Dr, Chicago, IL 60606.

using the previously validated 5-point Jadad scale<sup>22</sup> to assess the completeness and quality of reporting of RCTs as well as to assess for potential bias in the trial (Appendix 2). This widely used scale focuses on 3 dimensions of internal validity: quality of randomization, double blinding, and withdrawals.<sup>23</sup> This scale is the only published instrument that has been created according to psychometric principles.<sup>23,24</sup> A score is assigned from 0 to 5, with higher scores indicating higher quality in the conduct or reporting of the trial.<sup>22</sup> A trial scoring at least 3 out of 5 is considered to be of strong quality. Trials scoring below 3 are considered to be methodologically weak.

### Critical Appraisal

Each study also was critiqued using a rating system originally developed de Vet et al<sup>25</sup> in 1997. This rating system provides more detailed evaluation of the study methods and has been used previously in systematic reviews in physical therapy.<sup>26–29</sup> Specifically, this tool examines criteria relevant to the practice of physical therapy such as participant characteristics, sample size, description of interventions, and the validity and reliability of the chosen outcome measures (Appendix 3). The 2 investigators independently reviewed each study based on specific criteria of the rating scale. For each criterion, 3 rating categories were available: (1) pass—met criterion; (2) moderate—incomplete/partially met criterion; and (3) fail—did not meet criterion (the fail rating also was assigned if no information was provided in the publication on a specific criterion). Each quality criterion was evaluated separately. At present, there are no clear decision rules for establishing cutoff scores for high- and low-quality trials using this tool; therefore, summary scores were not used.<sup>30</sup>

### Results

The search of the literature resulted in a total of 1,138 published articles. No unpublished manuscripts were identified. Of the 1,138 published articles, 36 were considered to be potentially relevant. Independent review of these 36 articles led to the inclusion of 14 articles representing 12 studies.<sup>31–44</sup> Reasons for exclusion of the 22 studies<sup>45–66</sup> are provided in Table 1. The kappa ( $\kappa$ ) values for agreement between the raters were .88 for inclusion in the review and .76 for Jadad quality score. Only 3 of the included studies<sup>31,36,39</sup> were considered to be of strong methodological quality. Further details on the study characteristics are provided in Table 2 (page 717).

### Diagnosis

There was considerable diversity in the clinical presentation and diagnosis of participants with TMD among the included studies (Tab. 3, page 720). Six of the studies<sup>36,38,41–44</sup> examined the effectiveness of the physical therapy interventions in muscular TMD (myogenous TMD). Two studies<sup>31,32</sup> evaluated the effectiveness of

**Table 1.**  
Excluded Studies With Reasons for Exclusion

Authors	Reason(s) for Exclusion
Gray et al <sup>51</sup>	Not enough information on patient population; therefore, inclusion criteria were not met.
Talaat et al <sup>62</sup>	Inclusion criteria were not met.
Sporton <sup>61</sup>	It was not a clinical trial.
Maloney et al <sup>57</sup>	Not enough information patient population; therefore, inclusion criteria were not met.
Elsharkawy and Ali <sup>49</sup>	Not enough information on patient population; therefore, inclusion criteria were not met.
Carlson et al <sup>45</sup>	Inclusion criteria were not met.
Flor and Birbaumer <sup>50</sup>	Did not exclusively examine patients with temporomandibular disorder.
Magnusson and Syren <sup>56</sup>	Inclusion criteria were not met.
Michelotti et al <sup>58</sup>	Inclusion criteria were not met.
Michelotti et al <sup>59</sup>	Inclusion criteria were not met.
Cleland and Palmer <sup>46</sup>	Not a randomized controlled trial.
Zhou and Zhao <sup>65</sup>	Not enough information on study methods and participants.
Conti <sup>47</sup>	Inclusion criteria were not met.
Von Turp <sup>64</sup>	Not a clinical trial.
Peroz et al <sup>60</sup>	Inclusion criteria were not met.
Hansson and Ekblom <sup>52</sup>	Inclusion criteria were not met.
Hargreaves and Wardle <sup>53</sup>	Inclusion criteria were not met.
Johansson et al <sup>54</sup>	Inclusion criteria were not met.
Huang et al <sup>66</sup>	Inclusion criteria were not met.
Linde et al <sup>55</sup>	Inclusion criteria were not met.
van der Glas et al <sup>63</sup>	Not enough information on participants.
Dahlstrom <sup>33</sup>	Inclusion criteria were not met.

physical therapy treatments in patients with articular TMD (arthrogenous TMD), and 3 studies<sup>34,35,37,48</sup> investigated the use of physical therapy in patients with mixed diagnoses of TMD (included both myogenous and arthrogenous TMD). Six of the studies<sup>36,38,40–44</sup> used the research diagnostic criteria established by Dworkin and LeResche<sup>67</sup> to classify the patients as having myogenous TMD. One study<sup>31</sup> also used the research diagnostic criteria to establish the arthrogenous TMD diagnosis. The remaining studies used their own diagnostic criteria, based on signs and symptoms of the patients.

### Effectiveness of Exercise Interventions and Manual Therapy

Four studies<sup>32,37,38,40</sup> examined the effect of exercise interventions on TMD. The methodological quality of these 4 studies was considered weak (Tab. 2). Two studies examined the effect of posture training (in combination with other therapies) on myogenous TMD and reported significant improvements in pain and oral opening<sup>38,44</sup> in favor of the addition of postural exercise training. After 1 month, Komiyama et al<sup>38</sup> found a significant increase in mouth opening in patients who received postural training compared with patients receiving only

cognitive intervention or compared with the control group. Wright et al<sup>44</sup> found a statistically significant improvement in maximum pain-free opening, pain threshold, and the modified symptom severity index in patients receiving postural treatment compared with patients receiving self-management instructions alone.

Carmeli et al<sup>32</sup> compared the effect of manual therapy in combination with active exercise with the effect of treatment with occlusal splint therapy on anteriorly displaced temporomandibular disks in patients with arthrogenous TMD. The authors reported significant improvement in pain and oral opening in favor of the manual therapy/exercise group. The only study<sup>37</sup> reporting a nonsignificant finding from exercise examined the benefit of an oral exercise device on oral opening, pain, and wellness in patients with mixed TMD. In this study, Grace et al<sup>37</sup> reported finding no significant benefit from the addition of the oral exercise device to traditional therapies or when the oral exercise device was used as part of a home program.

#### *Effectiveness of Acupuncture Interventions*

Two studies<sup>36,40,41</sup> (1 weak study and 1 strong study) examined the use of acupuncture in the treatment of myogenous TMD. List and colleagues<sup>40,41</sup> (the weak study) assigned participants to 1 of 3 groups: acupuncture, occlusal splint therapy, or control. Significant differences in pain threshold, pain intensity, and clinical dysfunction score were found in favor of acupuncture compared with the control group. No significant differences, however, were found between the acupuncture and occlusal splint therapy groups. Goddard et al<sup>36</sup> (the strong study) evaluated the effect of acupuncture compared with sham acupuncture and found no significant difference in pain threshold response between the groups.

#### *Effectiveness of Electrophysical Modalities*

Six studies<sup>31,34,35,39,42,43,48</sup> (2 strong studies and 4 weak studies) examined the efficacy of various electrophysical modalities in the treatment of TMD pain and dysfunction. There was considerable heterogeneity among the studies in the type of TMD, the chosen modality and comparison group, and in the frequency and duration of the treatment (Tab. 2). In the study by Al-Badawi et al<sup>31</sup> (a strong study), 6 treatments of pulsed radio-frequency energy (PRFE) therapy were not found to be significantly better than sham PRFE for arthrogenous TMD. Treacy<sup>42</sup> (a weak study) reported that 20 sessions of TENS were not significantly better than muscular awareness relaxation therapy (MART) or sham TENS. Significant improvements were found, however, in oral opening and electromyographic activity for the MART group when compared with treatment with TENS and sham TENS.

Wieselmann-Penkner et al<sup>43</sup> (a weak study) reported that 3 sessions of TENS were not significantly better in improving pain for myogenous TMD compared with biofeedback. In the studies by Dalhstrom and colleagues<sup>34,48</sup> and Funch and Gale<sup>35</sup> (2 weak studies), biofeedback was not found to be significantly better in reducing pain when compared with relaxation therapy or occlusal splint therapy. Biofeedback training, however, did result in significant improvement in oral opening when compared to occlusal splint therapy.<sup>34,48</sup> Kulekcioglu et al<sup>39</sup> (a strong study) reported significant improvements in active and passive oral opening and in lateral deviation range of motion, following 15 sessions of low-level laser therapy compared with sham laser. In the same study, however, no significant differences were found in pain reduction between the groups.

#### *Adverse Events*

Adverse events were reported only in the study by Al-Badawi et al.<sup>31</sup> The authors reported skin irritation or color changes at the application site of the PRFE during treatment in 4 participants. The authors also reported that the device made an irritating high-pitched sound that required the use of earplugs during treatment sessions.

#### **Discussion and Critical Appraisal**

In the present systematic review, many publications were found that addressed treatment of TMD; however, few published studies met the criteria for inclusion in the review. The requirement for RCTs and the criteria established for the type of participants eliminated many potential studies for review. Many of the studies in this review were considered methodologically weak when evaluated by the Jadad scale and further limitations were identified through the critical appraisal process (Tab. 4, page 721).

#### *Exercise and Manual Therapy*

Exercise therapy has long been used in the treatment of TMDs. Therapeutic exercise interventions are prescribed to address specific TMJ impairments and to improve the function of the TMJ and craniomandibular system.<sup>68</sup> Most exercise programs are designed to improve muscular coordination, relax tense muscles, increase range of motion, and increase muscular strength (force-generating capacity).<sup>69</sup> The most useful techniques for re-education and rehabilitation of the masticatory muscles have been reported as manual therapy, muscle stretching, and strengthening exercises.<sup>70</sup> Passive and active stretching of muscles or range-of-motion exercise are performed to increase oral opening and decrease pain.<sup>70</sup> Postural exercises also are recommended to restore or optimize the alignment of the craniomandibular system.<sup>8</sup>

Two of the 12 selected studies in this systematic review evaluated the effectiveness of postural correction exercises for patients with TMDs.<sup>38,44</sup> Both of these studies examined patients with myogenous TMD and used the research diagnostic criteria of Dworkin and LeResche<sup>67</sup> to establish the diagnosis. The positive findings of these 2 studies (reduced pain and improved oral opening), therefore, can be generalized to this specific group of patients and is in line with the present approach for treatment of TMD.<sup>71-73</sup> From a methodological point of view, the study by Wright et al<sup>44</sup> was considered a weak study according to the Jadad score; however, this study provided considerably more detail (ie, randomization, blinding, sample size, good control of potential confounders) than the other studies included in this review. The main concern with this study was that the treatment protocol was not described in enough detail to allow for replication of the intervention. In the study by Komiya et al,<sup>38</sup> both the Jadad quality assessment and in the critical appraisal identified numerous concerns. In particular, the article lacked details on the method of randomization, postural exercise protocol, chosen outcome measures, and agreement to participate.

Only one study, by Carmeli et al,<sup>32</sup> was designed to evaluate exercise in patients with articular TMD. The authors compared the effects of a manual therapy and exercise program with the use of a repositioning splint in participants with an anterior displaced temporomandibular disk. The results of this study support the use of the combined manual therapy and exercise to reduce pain and increase range of motion. Overall, however, this study was considered methodologically weak. Furthermore, the study sample size was small, the mobilization protocol was not described in enough detail to allow replication, and no information was provided on the validity and reliability of the chosen outcomes measures.

Grace et al<sup>37</sup> evaluated the use of an oral exercise device in the treatment of patients with mixed TMD. The authors analyzed 3 groups: the first group received traditional therapies; the second group received traditional therapy and an oral exercise device; and the third group received education and instruction in home care and the use of an oral exercise device. This study, although described as an RCT, sequentially assigned participants to treatment groups. Further limitations of this study included a poor description of baseline characteristics of participants (eg, medication use, previous treatment), a small sample size, and the fact that the chosen interventions included multiple treatments. The use of multiple uncontrolled treatments in this study clouds any conclusions about the relative effectiveness of the oral exercise device.

Despite these methodological limitations, the evidence in support of manual therapy and oral and postural

exercises to reduce pain and improve range of motion is of definite clinical interest.<sup>33,37</sup> More information, however, is required on the optimal exercise prescription. In particular, details on frequency, intensity, and time and type of the specific exercise used in treatment protocols is essential to allow for replication in the clinical setting.

## Acupuncture

Acupuncture is increasingly being used in the treatment of musculoskeletal conditions in North America.<sup>74</sup> At present, the mechanisms underlying the action of acupuncture are unclear.<sup>75</sup> Acupuncture may stimulate the production of endorphins, serotonin, and acetylcholine within the central nervous system, or it may relieve pain by acting as a noxious stimulus.<sup>75,76</sup>

Both studies<sup>36,40,41</sup> included in this systematic review reported improvements in pain with acupuncture treatment; however, acupuncture was not found to be significantly better than sham acupuncture or occlusal splint therapy. The study by Goddard et al<sup>36</sup> found that pain improved with a single treatment of either traditional or sham acupuncture. Although a within-group difference was found in the group receiving traditional acupuncture, the difference between the groups was not statistically significant. The study was considered strong by the Jadad scale; however, the small sample size of the study (n=16) would suggest that the study was inadequately powered to detect a difference between the groups.

The study by List and colleagues<sup>40,41</sup> examined the effect of 6 to 8 treatments of acupuncture. Although the authors reported that acupuncture was significantly better than no treatment in reducing pain, no significant differences were found between acupuncture and occlusal splint therapy. The study was considered weak by the Jadad criteria and was deficient in a number of criteria on the critical appraisal: there was inadequate information on baseline characteristics of participants (eg, medication use), agreement to participate, and data collection methods (eg, validity and reliability of outcome measures). Furthermore, independent assessors were not used to administer outcome measures. Given the methodological concerns of studies by Goddard et al<sup>36</sup> and List and colleagues,<sup>40,41</sup> further research in this area is warranted before ruling out any potential effect of acupuncture treatment.

## Electrophysical Modalities

Electrophysical modalities, such as shortwave diathermy, ultrasound, laser, and TENS, are commonly performed in the clinical setting.<sup>51</sup> Electrophysical modalities are intended to reduce inflammation, promote muscular relaxation, and increase blood flow by altering capillary permeability.<sup>51</sup> The literature suggests that treatments with electrophysical modalities, performed early in the

course of a TMD, are beneficial in reducing symptoms.<sup>51</sup> The studies included in this review<sup>31,34,35,39,42,43,48</sup> examined the benefits of various electrophysical modalities including PRFE, biofeedback, laser therapy, and TENS. Comparison interventions included no treatment control, sham treatment, relaxation therapy, occlusal splint therapy, and behavioral management. No evidence was found to support the use of any of the electrophysical modalities to reduce pain. The significant benefits reported from the use of electrotherapeutic modalities were increased oral opening and lateral deviation range of motion measures.

**PRFE.** The study by Al-Badawi et al<sup>31</sup> examined the effect of PRFE on pain, oral opening, and lateral deviations. This study was considered strong by the Jadad criteria. The concerns with this study were that the authors did not provide information on agreement to participate, sample size calculation, or on the validity and reliability of chosen outcome measures. Based on this small study, at present, there is no evidence to support the use of PRFE to reduce pain in arthrogenous TMD. The within-group improvement in oral opening and lateral deviations found with PRFE treatment, however, suggests the need for evaluation with a larger sample size.

**TENS.** The studies performed by Treacy<sup>42</sup> and Wieselmann-Penkner et al<sup>43</sup> that examined the efficacy of TENS were considered to be methodologically weak, and the sample sizes in these 2 studies were small. Numerous other concerns were identified with these studies (Tab. 4); therefore, further research is warranted before dismissing any effect of TENS. In the study performed by Treacy, improvement in oral opening and electromyographic activity occurred in the comparison group receiving MART; however, this finding is based on a single, small, poor-quality study.

**Biofeedback.** The studies examining biofeedback that were performed by Dahlstrom and colleagues<sup>34,48</sup> and Funch and Gale<sup>35</sup> also were considered weak. Furthermore, our critical appraisal of these studies identified numerous concerns with the design and reporting of trial methods. Dahlstrom and colleagues did report significant improvement in oral opening with biofeedback; however, the study did not use independent assessors and few details were provided on data collection methods.

**Laser therapy.** Kulekcioglu et al<sup>39</sup> reported significant improvements in active and passive oral opening and in lateral deviation range of motion with laser therapy treatment and was considered strong by Jadad criteria. Although the study also included use of independent outcome assessment, no details were provided on agreement to participate, on sample size calculation, on data collection methods, or on the number of participants starting and finishing the study.

## Limitations

Although this systematic review is the first to investigate the effectiveness of physical therapy interventions in patients with TMD, the review does have some limitations that need to be acknowledged. The findings of this review are specific to TMD (nonsurgical) and to the field of physical therapy. As with any systematic review, there is the potential for selection bias; however, we used a comprehensive search strategy and included publications in any language. In addition, 2 independent reviewers were used, and reasons for study exclusions were clearly documented. Although attempts were made to identify unpublished studies, no such studies were found.

The heterogeneity among studies, particularly with respect to the TMD diagnosis, study intervention, and chosen control/comparison intervention, was a challenge of this review. This diversity, as well as the small sample sizes and poor methodological quality of many of the studies, limits overall conclusions and highlights the need for further research.

## Conclusions

### Implications for Practice

The results of this systematic review support the use of active and passive oral exercises and exercises to improve posture as effective interventions to reduce symptoms associated with TMD. More information on the exercise prescription, however, is necessary to allow for replication in clinical setting. At present, there is inadequate information to either support or refute the use of acupuncture in the treatment of TMD. There is no evidence to support the use of electrophysical modalities to reduce TMD pain; however, the evidence suggests improvements in oral opening may result from treatment with MART, biofeedback training, and low-level laser therapy treatment. Most of the studies included in this review were of very poor methodological quality; therefore, these findings must be interpreted with caution.

### Implications for Research

There is a clear need for well-designed RCTs examining physical therapy interventions for TMD. Trials should be large enough to be clinically meaningful, adequately powered, and include valid and reliable outcome measures. Furthermore, attempts should be made to blind assessors performing outcome measures and, where possible, the participants as well. Investigators should consider the findings of this systematic review when designing trials and attempt to overcome the limitations of the studies presented. Based on the positive effects of active and passive exercise, postural exercises, and manual therapy, high-quality trials with larger sample sizes are clearly warranted in these areas.

**Table 2.** Study Characteristics of Physical Therapy Interventions for Temporomandibular Disorders<sup>a</sup>

<b>A. Exercise Interventions</b>							
<b>First Author, Year, Location</b>	<b>Participants</b>	<b>Intervention and Control/Comparison Groups</b>	<b>Frequency and Duration</b>	<b>Primary End Points</b>	<b>Results</b>	<b>Authors' Conclusions</b>	<b>Quality Score</b>
Carmeli et al, <sup>32</sup> 2001 Israel	N=36 Sex: 26 female, 10 male Age: 19-43 y	Manual mobilization and active exercises vs Soft, flat-plane occlusal repositioning splint	4 wk treatment: Manual therapy every 2nd or 3rd day; active exercises 4-6x per day for 5 min duration Splint worn 24 hr/d	Active range of motion; oral opening Pain scale: 0="no pain" to 5="severe pain"	Manual therapy and exercises significantly better than splint in reducing pain ( $P<.05$ ) and improving oral opening ( $P<.05$ )	Manual mobilization and active exercises more effective to improve pain and range of motion than soft repositioning splint	Jadad score: 1 Randomized: yes Described: no Double blind: no Blinding described: no Withdrawals: no
Grace et al, <sup>37</sup> 2002 USA	N=45 Sex: 38 female, 7 male Age: 18-76 y (mean=39.1 y)	Traditional therapies <sup>b</sup> vs Traditional plus oral exercise device vs Oral exercise device: (Facial flex device <sup>c</sup> )	2x per week for 2 mo Oral device: 2x per day for 1-2 min at a time; resistance progressed	Oral opening and lateral deviation (mm) Pain VAS: 0="no pain" to 10="very painful" (3 time points: today; over last week; predict next week) Joint noises: auscultation with stethoscope Wellness scale: 5 questions	No statistically significant differences within/ between groups for any outcomes	Further research needed: increased exercise times and larger sample size	Jadad score: 1 Randomized: yes Described: no Double blind: no Blinding described: no Withdrawals: yes Deducted 1 point for sequential assignment to groups
Komiyama et al, <sup>38</sup> 1999 Japan	N=60 Sex: 49 female, 11 male Age: mean=26 y	Cognitive behavioral (CB): education on chronic pain, stress reduction, and relaxation training vs CB with posture correction: posture group also received posture training at each session vs Control group	1 session per month for 12 mo; both intervention groups	Oral opening (pain-free range of motion) Pain intensity at maximum mouth opening (VAS 100-mm scale) Disturbance in daily life (VAS 100-mm scale)	Posture group had a statistically significant improvement in oral opening compared to control ( $P<.05$ ) at all time points Pain: both intervention groups significantly better than control at 6 and 9 mo ( $P<.05$ ) Disturbance in daily life: both intervention groups significantly better than control group at 6 mo ( $P<.05$ ) No statistically significant difference between groups for any outcomes at 12 mo	Posture correction in daily life has a positive effect on myofascial pain associated with limited mouth opening	Jadad score: 2 Randomized: yes Described: no Double blind: no Blinding described: no Withdrawals: yes
Wright et al, <sup>44</sup> 2000 USA	N=60 Sex: 51 female, 9 male Age: 18-60 y	TMD self-management instructions alone (rest masticatory muscles, avoid parafunctional habits, apply heat or cold, use nonprescription anti-inflammatory medications) vs Posture training and TMD self-management instructions	4 wk duration Posture group: 2 sessions with physical therapist Each exercise had specific instructions for number of repetitions	Maximum pain-free oral opening (mm) Pain threshold: with pressure algometer at 2 points (masseter and trapezius muscles in kg/cm <sup>2</sup> ) Modified symptom severity index (5 VAS each for TM) and neck	Maximum pain-free opening significantly greater improvement in posture group ( $P<.05$ ) There was a statistically significant improvement in the modified symptom severity index for both TM and neck ( $P<.001$ ) in favor of posture group	Posture training and TMD self-management together are more effective than self-management alone for muscular TMD	Jadad score: 2 Randomized: yes Described: yes Double blind: no Blinding described: no Withdrawals: no

(continued)

**Table 2.**  
Continued

<b>B. Acupuncture</b>		<b>Intervention and Control/Comparison Groups</b>	<b>Frequency and Duration</b>	<b>Primary End Points</b>	<b>Results</b>	<b>Authors' Conclusions</b>	<b>Quality Score</b>
<b>First Author, Year, Location</b>	<b>Participants</b>						
Goddard et al, <sup>36</sup> 2002 USA	N=18 Sex: 15 female, 3 male Age: 22-52 years	Acupuncture (4 specific points; depth 10-30 mm) vs Sham acupuncture (4 sham points; depth 2-4 mm)	Single session: 30 min	Pain: 100-mm VAS (maximal pain evoked by mechanical stimulus using algometer)	No significant differences between the groups (P=.255) Within-group reduction in pain (P=.001) for acupuncture points or in other areas	Pain reduction resulting from needling may not be dependent on whether needling is performed in standard acupuncture points or in other areas	Jadad score: 5 Randomized: yes Described: yes Double blind: yes Blinding described: yes Withdrawals: yes
List et al, <sup>40,41</sup> 1992/1993 Sweden	N=55 Sex: 46 female, 9 male Age: 22-69 y	Acupuncture vs Occlusal splint therapy vs Control	6-8 wk duration Acupuncture: 6-8 treatments of 30 min duration, 1x/week Splints: worn at night for 7-8 wk Control: wait list (pain diaries used)	Pain threshold (algometer) in kg/cm <sup>2</sup> /s Clinical dysfunction score (CDS): included oral opening, function, palpation of TMJ and masticatory muscles, and pain with movement Pain intensity: 100-mm VAS ("no pain" to "worst pain imaginable")	Significant differences between the 2 treatment groups and control group for pain (P<.05), CDS (P<.01), and pain intensity (P<.01) No significant differences between treatment groups following treatment (P value not provided in article)	Acupuncture and occlusal splint therapy have a significant effect on pain threshold, CDS, and pain intensity in patients with TMD	Jadad score: 2 Randomized: yes Described: no Double blind: no Blinding described: no Withdrawals: yes
<b>C. Electrophysical Modalities</b>							
Al-Badawi et al, <sup>31</sup> 2004 USA	N=40 Sex: 31 female, 9 male Age: 22-55 y	Pulsed radio-frequency energy therapy (PRFE): 6 treatment units of 1.5 s each with 7-s rest vs Sham PRFE	2 wk duration Treatment once per day, every 2nd day for a total of 6 treatments	Pain: numeric rating scale (0="no pain," 10="pain as bad as it can be") Oral opening and lateral deviations: Therabite measuring scale (mm)	No significant differences between the groups. A significant reduction in pain over time in both groups. The PRFE group showed a significant increase in mouth opening and lateral deviations.	PRFE is a safe and effective treatment for TMJ arthralgia	Jadad score: 3 Randomized: yes Described: no Double blind: yes Blinding described: yes Withdrawals: no
Dahlstrom and colleagues, <sup>33,34</sup> 1982/1984 Sweden	N=30 Sex: 30 female Age: 20-40 y (mean=28.6 y)	Biofeedback vs Occlusal splints	6 weeks duration Biofeedback: 30-min treatments, 6x Splints worn at night for 6 wk	Clinical dysfunction score (1=none, 5=very severe) Oral opening	No significant differences between the groups Maximal oral opening significantly increased only in the biofeedback group (within-group difference P<.01)	The 2 treatments were equally effective in the short term	Jadad score: 2 Randomized: yes Described: yes Double blind: no Blinding described: no Withdrawals: no
Funch and Gale, <sup>35</sup> 1984 USA	N=57 Sex: 51 female, 6 male Age: mean=39.5 y	Biofeedback (specific to site of pain) vs Relaxation therapy (tape-recorded relaxation sequence)	12 wk duration, 1x per week Patients encouraged to practice relaxation (specific or general) daily at home	Post-treatment and 2-y follow-up Pain: 6-point scale (0="no pain at all" to 6="pain severe enough to interfere with behavior, and to be incapacitating"), collected weekly	No significant differences between the groups	Knowledge of pretherapy factors, particularly clinical, may allow for more optimal assignment to treatment	Jadad score: 1 Randomized: yes Described: no Double blind: no Blinding described: no Withdrawals: no

(continued)

**Table 2.**  
Continued

First Author, Year, Location	Participants	Intervention and Control/Comparison Groups	Frequency and Duration	Primary End Points	Results	Authors' Conclusions	Quality Score
Kulekcioglu et al, <sup>39</sup> 2003 Turkey	N=35 Sex: 28 female, 7 male Age: 20-59 y (mean=37 y)	Gallium-arsenide low-level laser therapy (LLLT) with daily range of motion, stretching, and posture exercises vs Placebo (sham laser) with daily range of motion, stretching, and posture exercises	Duration: not stated; 15 sessions Daily exercises both groups	Pain: 100-mm VAS Oral opening and lateral deviations: ruler (mm) Joint sounds: auscultation Number of tender points: palpation	No significant differences between the groups in pain reduction Significant improvement in favor of LLLT for active and passive oral opening ( $P<.01$ , $P<.01$ ), right and left lateral deviations ( $P<.006$ , $P<.001$ ), and number of tender points ( $P<.006$ ) after treatment (significant effect at 1-mo follow-up as well)	LLLT in combination with exercise can be considered as an option in management of TMD Treatment effects were similar in myogenic and arthrogenic cases	Jadad score: 3 Randomized: yes Described: no Double blind: yes Blinding described: yes Withdrawals: no
Treacy, <sup>42</sup> 1999 Sweden	N=24 Sex: 10 female, 14 male Age: 20-38 y (mean=25 y)	Muscular awareness relaxation training (MART) vs Transcutaneous electrical nerve stimulation (TENS) vs Sham TENS	4 mo duration 20 treatment sessions of 30 min duration, twice a week: all groups	Electromyographic activity Discomfort: 6-point scale (0="absence of discomfort" to 6="great discomfort") Oral opening Breaths per minute	No significant difference in change in discomfort between groups MART group significantly improved oral opening compared with other groups (TENS group: $P<.05$ , sham TENS group: $P<.01$ ), electromyographic activity for pterygoid/masseter tension ( $P<.05$ ) and frontalis muscle ( $P<.01$ ) and decrease in breaths per minute ( $P<.05$ )	MART superior to TENS and sham TENS in decreasing muscular tension when treatment is administered 2X per week for 4 mo	Jadad score: 1 Randomized: yes Described: no Double blind: no (single only) Blinding described: no Withdrawals: no
Wieselmann-Penkner et al, <sup>43</sup> 2001 (pilot study) Austria	N=20 Sex: 13 women, 7 men Age: 22-58 y	Electromyographic biofeedback to relax masseter and temporalis muscles vs TENS	1-wk duration, 3 sessions per group	Electromyographic activity Skin conductance level	No significant differences between groups Trend for decreased mean electromyographic levels for both groups after treatment sessions Increase in skin conductance levels during treatment for both groups in sessions I and II which stabilized for session III	Both treatments lead to local relaxation of masticatory muscles	Jadad score: 1 Randomized: yes Described: no Double blind: no Blinding described: no Withdrawals: no

<sup>a</sup> VAS=visual analog scale, TMD=temporomandibular disorder, TMJ=temporomandibular joint.

<sup>b</sup> Traditional therapies were stated to include any of the following: oral stabilization appliances, medications, home physical therapy or exercises, patient education, stress reduction therapy, and therapy or physical modalities.

<sup>c</sup> Facial Concepts Inc, PO Box 99, Blue Bell, PA 19422 ([http://www.facialconcepts.com/newsite/tmd\\_therapy.htm](http://www.facialconcepts.com/newsite/tmd_therapy.htm)).

**Table 3.**Classification of Studies According to Diagnosis<sup>a</sup>

<b>Muscular Temporomandibular Disorders</b>	<b>Articular Temporomandibular Disorders</b>	<b>Mixed Temporomandibular Disorders</b>
Komiyama et al <sup>38</sup> : myofascial pain with limited opening according to Dworkin and LeResche <sup>67</sup>	Carmeli et al <sup>32</sup> : diagnosis of anterior temporomandibular disks with unstable excursive reduction (no further details provided)	Grace et al <sup>37</sup> : TMJ dysfunction with a primary diagnosis of muscular dysfunction (51.1% of patients); however, 42.2% had a secondary diagnosis of a functional problem (reducing disk displacement) and 6.7% had a secondary diagnosis of an inflammatory TMD
Wright et al <sup>44</sup> : TMD research diagnosis criteria for muscle disorders according to Dworkin and LeResche <sup>67</sup>	Al-Badawi et al <sup>31</sup> : patients had a clinical diagnosis of arthralgia as defined by the research diagnostic criteria of Dworkin and LeResche <sup>66</sup>	Dahlstrom et al <sup>33</sup> and Dahlstrom and Carlsson <sup>34</sup> : signs and symptoms of mandibular dysfunction (ie, TMJ sounds, feeling stiffness of the jaw and fatigue, facial and jaw pain, locking, pain on movement of the jaw)
Goddard et al <sup>36</sup> : myofascial pain according to Dworkin and LeResche <sup>67</sup>		Funch and Gale <sup>35</sup> : chronic TMJ pain, not specific whether pain was myogenous or arthrogenous
Treacy <sup>42</sup> : patients were diagnosed as having bruxism based on the criteria of Phillips et al <sup>6</sup>		Kulekcioglu et al <sup>39</sup> : patients had orofacial pain, TMJ sounds, limited mouth opening, or TMJ locking, tenderness in masticatory and cervical muscles
Wieselmann-Penker et al <sup>43</sup> : patients were diagnosed as having bruxism according to the following criteria: <ul style="list-style-type: none"> <li>• Pain and tenderness to palpation of the masticatory muscles with a chronicity of at least 6 mo</li> <li>• No evidence of joint pathology based on clinical examination and radiographs</li> </ul>		
List and colleagues <sup>40</sup> : signs and symptoms of CMD of primarily muscular origin		

<sup>a</sup> TMJ=temporomandibular joint, TMD=temporomandibular disorder, CMD=craniomandibular disorder.<sup>b</sup> Phillips DJ Jr, Walters PJ, Rogal OJ, et al. Recommended guide to the evaluation of permanent impairment of the temporomandibular joint. *Cranio*. 1989;7:13-21.

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**Table 4.**  
Critical Appraisal of Included Studies by Group<sup>a</sup>

Primary Author and Year	1	2	3	4	5	6	7	8	9	10	Main Concerns
<b>Exercise</b>											
Carmeli et al, <sup>32</sup> 2001	P	M	F	M	F	F	P	P	M	P	Agreement to participate Sample size Validity and reliability of outcome measures
Grace et al, <sup>37</sup> 2002	P	M	M	F	F	F	F	M	M	M	Intervention not well described Sample size Validity and reliability of outcome measures Blinded assessors not used
Komiyama et al, <sup>38</sup> 1999	P	P	F	M	M	F	P	P	M	P	Agreement to participate Validity and reliability of outcome measures
Wright et al, <sup>44</sup> 2000	P	P	P	M	M	M	P	P	P	P	More detail on interventions and data collection methods
<b>Acupuncture</b>											
Goddard et al, <sup>36</sup> 2002	P	P	M	M	F	M	P	P	P	P	Sample size
List and colleagues, <sup>40,41</sup> 1992/1993	P	F	F	P	M	F	F	P	M	P	Significant differences between groups in baseline characteristics Agreement to participate Validity and reliability of outcome measures Blinded assessors not used
<b>Electrophysical Modalities</b>											
Al-Badawi et al, <sup>31</sup> 2004	P	M	F	M	M	F	M	P	M	P	Agreement to participate Validity and reliability of outcome measures
Dahlstrom and colleagues, <sup>33,34</sup> 1982/1984	P	F	F	M	F	F	F	P	M	M	Baseline characteristics poorly described Agreement to participate Sample size Validity and reliability of outcome measures Blinded assessors not used
Funch and Gale, <sup>35</sup> 1984	P	M	F	M	M	F	F	P	M	M	Agreement to participate Validity and reliability of outcome measures Blinded assessors not used
Kuleklioglu et al, <sup>39</sup> 2003	P	M	F	M	F	F	M	F	M	P	Agreement to participate Sample size Validity and reliability of outcome measures Participants starting and finishing
Treacy, <sup>42</sup> 1999	P	M	F	M	F	F	M	P	M	P	Agreement to participate Sample size Validity and reliability of outcome measures
Wieselmann-Penkner et al, <sup>43</sup> 2001	P	F	F	M	F	F	F	F	M	P	Baseline characteristics poorly described Agreement to participate Sample size Validity and reliability of outcome measures Blinded assessors not used Participants starting and finishing

<sup>a</sup> 1=study design, 2=baseline characteristics, 3=agreement to participate, 4=intervention, 5=sample size, 6=data collection methods, 7=blinding, 8=participants starting/finishing, 9=external validity, 10=statistical tests. P=pass, met criterion; M=moderate, incomplete/partially met criterion, F=fail, did not meet criterion (the fail rating was also assigned if no information was provided in the publication on a specific criterion).

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## Appendix 1.

Physical Therapy Effectiveness Project Relevance Tool—Primary Studies

		<b>Ref ID:</b> _____ <b>Year:</b> _____ <b>Reviewer:</b> _____ <b>MM</b> <b>SAO</b> <b>Other:</b> _____
STUDY: Physical Therapy Intervention for Temporomandibular Disorders		
<b>INSTRUCTIONS FOR COMPLETION:</b>		
1. Circle Y or N for each relevance criterion 2. Record inclusion decision: article must satisfy all relevant criteria 3. Ensure that no exclusion criteria are included 4. Record if additional references are to be retrieved 5. Complete validity form for articles to be included		
<b>RELEVANCE CRITERIA:</b>		
1. Does this article evaluate a physical therapy intervention or program?	Y	N
2. Is the intervention within the scope of physical therapist practice?	Y	N
3. Are the participant inclusion criteria covered?		
a. Clinical diagnosis of temporomandibular disorder	Y	N
b. Age: adult >18 years	Y	N
c. Musculoskeletal problem	Y	N
d. Pain impairment	Y	N
e. No other serious comorbid conditions	Y	N
4. Not examining a postsurgical intervention for temporomandibular dysfunction	Y	N
5. Are one or more appropriate outcomes measured (eg, range of motion, pain, functional outcome measure, quality of life, patient satisfaction, muscular activity, electromyography)?	Y	N
6. Is the article a randomized controlled trial (described as random/randomized/random allocation/random assignment)?	Y	N
<b>REVIEWER DECISION:</b>		
1. Include in critical appraisal (Yes=Y to all relevance criteria) If yes, please complete validity form	Y	N
2. Additional references If yes, mark items on reference list of article	Y	N
<b>IF DISCREPANCY IN INCLUSION DECISION:</b>		
Reason for discrepancy:		
Oversight	Y	N
Differences in interpretation of criteria	Y	N
Differences in interpretation of study	Y	N
<b>FINAL DECISION: INCLUDE IN STUDY</b>	<b>Y</b>	<b>N</b>

## Appendix 2.

Scoring of Jadad Scale

Score: Assign a score of 1 point for each "yes" or 0 points for each "no."	
1. Was the study described as randomized (this includes the use of words such as randomly, random, and randomization)?	
2. Was the study described as double-blind (blinding of patients and evaluators, not necessarily therapists)?	
3. Was there a description of withdrawals and dropouts (explicit statement that all included patients were analyzed or if the number and reasons for dropouts in all groups are given separately)?	
Give 1 additional point if:	
For question 1, the method to generate the randomization sequence was described and appropriate (table of random numbers, computer generated).	
For question 2, the method of double blinding was described and it was appropriate (independent blinded assessors used, identical placebo or active placebo treatment, neither the person doing the assessments nor the study participant could identify the intervention being assessed).	
Deduct 1 point if:	
For question 1, the method to generate the randomization sequence was described and was <i>inappropriate</i> (alternate allocation to groups or according to date of birth, hospital number, etc).	
For question 2, the method of blinding was <i>inappropriate</i> (the person doing the assessment and/or the study participant could identify the intervention being assessed).	

### Appendix 3.

#### Critical Appraisal—Included Studies<sup>a</sup>

STUDY: Interventions for Temporomandibular Disorders (Included Studies)				
<b>1. Type of Study</b>			<b>6. Data Collection Methods (continued)</b>	
i. Random	(P)		<i>Functional outcome (questionnaire or others)<sup>e</sup></i>	
ii. Pre-experimental/quasi-random	(M)		● Reliable test instrument	Y N
iii. Case control/cross-sectional	(F)		● Valid test instrument	Y N
iv. Descriptive	(F)		● Sensitive	Y N
			● Well described	Y N
<b>2. Baseline Characteristics<sup>b</sup></b>			<i>Clinician performed (range of motion, functional outcome)</i>	
i. Sex	Y N		<i>Do this for each clinician performed test<sup>f</sup></i>	
ii. Age	Y N		● Interrater reliability	Y N N/A
iii. Medication	Y N		● Intrarater reliability	Y N
iv. Simultaneous treatment	Y N		● Reliable test instrument	Y N
			● Valid test instrument	Y N
<b>3. Agreement to Participate</b>			● Sensitivity	Y N
i. >80%	(P)		● Well described	Y N
ii. 60–80%	(M)			
iii. <60%	(F)		<b>7. Blinding<sup>g</sup></b>	
iv. Cannot tell	(F)		Patients	Y N N/A
<b>4. Intervention</b>			Clinicians	Y N N/A
i. Range of motion/stretching			Assessors	Y N
ii. Modality: _____				
iii. Mobilization			<b>8. Participants Starting and Finishing Study</b>	
iv. Strength/resistance exercise training			i. Immediate	>80% (P)
v. Other, please specify _____				60–80% (M)
				<60% (F)
<b>Physical Therapy Treatment was<sup>c</sup>:</b>			ii. Posttreatment	>80% (P)
i. Well described	Y N			60–80% (M)
ii. Specific to tested groups	Y N			<60% (F)
iii. Co-intervention avoided	Y N		iii. Follow-up	>80% (P)
iv. Compliance/adherence	Y N	N/A		60–80% (M)
				<60% (F)
<b>5. Sample Size Was:</b>			<b>9. External Validity<sup>h</sup></b>	
i. Appropriate: a priori effect size/power	(P)		i. Clinically important outcomes?	Y N
ii. Appropriate, no justification provided	(M)		ii. Results applicable to clinical setting (ie, treatment benefits worth potential harms/costs)?	Y N
iii. Small, justification provided (pilot)	(M)		iii. Patients similar to clinical setting for demographics, severity, comorbidity, and other prognostic factors?	Y N
iv. Small and no justification provided	(F)		iv. All participants accounted for at conclusion?	Y N
<b>6. Data Collection Methods</b>			<b>10. Were there statistical tests of the intervention effects?<sup>i</sup></b>	
<i>Self reported<sup>d</sup></i>			i. Appropriate/suitable statistical tests	Y N
● Reliable test instrument	Y N		ii. Precision and variability (eg, P value and confidence interval)	Y N
● Valid test instrument	Y N			
● Sensitive	Y N			
● Well described	Y N			

<sup>a</sup> P=pass, met criterion; M=moderate, incomplete/partially met criterion, F=fail, did not meet criterion (the fail rating was also assigned if no information was provided in the publication on a specific criterion).

<sup>b</sup> If differences in baseline characteristics between groups were statistically controlled, P=3 or all, M=2, F=0–1.

<sup>c</sup> P=all, M=1–3, F=0. Well described: dosage, time, placement.

<sup>d</sup> P=all, M=1–3, F=0.

<sup>e</sup> Outcome: P=all, M=validity+(2–3), F=no validity or 0–1, N/A is not a fail for this category.

<sup>f</sup> P=6 or all, M=validity+(2–5), F=validity+(0 or 2), N/A is not a fail for this category. Scoring for outcome measure: P=all outcomes received a score of P, M=1–2 outcomes received a score of P, F=none of the outcome measures met all criteria.

<sup>g</sup> P=all, M=1, F=0, N/A is not a fail for this category.

<sup>h</sup> P=all, M=1–3, F=0.

<sup>i</sup> P=all, M=1, F=0.