Stomatologija, Baltic Dental and Maxillofacial Journal, 20: 3-9, 2018

Quality of life in patients with temporomandibular disorders. A systematic review

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SUMMARY

Objective. The purpose of this study was to systematically review the literature concerning the quality of life of patients with temporomandibular joint disorder.

Material and methods. Systematic review was performed with the information contained in international databases: PubMed and Google Scholar. Keywords and their combinations were used to find relevant articles and publications concerning the subject.

Results. A total of 320 publications were initially retrieved. After further examination 12 articles were selected due to their relevance to inclusion criteria and were included in the systematic review. The selected 12 articles published between year 2006 and 2016.

Conclusion. In this systematic review it was found that there is a direct correlation between temporomandibular disorders and lower quality of life. Out of questionnaires used for identification of patient satisfaction SF-36 and OHIP-14 were most popular in these studies. Statistical analysis of studies mentioned lead us to believe that psychological and physical ailments caused by TMD result in lower quality of life in patients.

Key words: quality of life, temporomandibular joint disorders, temporomandibular dysfunction.

INTRODUCTION

Temporomandibular disorder (TMD) is a general term given for an illness involving a series of clinical signs and symptoms concerning masticatory muscles, temporomandibular joints (TMJ) and associated structures (1).

Most common TMD signs and symptoms are chronic pain, jaw muscle soreness, limited range of jaw movement and temporomandibular joint noises (2). Majority of pain reported by patients is located in masticatory muscles and/or pre-auricular region, this can be easily exacerbated by chewing or other jaw activity (1). Other symptoms include, but are not limited to joint noises, jaw movement asymmetry, commonly described as clicking, popping, grating, or crepitus (3-5), painless masticatory muscles hypertrophy, muscle fatigue (1), also a wide variety of symptoms including headache, bruxism, tenderness upon palpation and difficulty opening the mouth due to limited range of movement (3, 4). Our selected studies show that the main cause of non-dental pain in the orofacial region are musculoskeletal conditions related to cervical regions, as well as masticatory musculature, while longitudinal studies have shown that the progression of pain severity is uncommon (6).

Temporomandibular disorders can have a wide variety of causes, among which, most common are: parafunctional habits, occlusal disharmony, stress, anxiety, trauma and microtrauma, mandibular instability, postural imbalance and abnormal physiological conditions (7). Several factors including sleep disorders as well as physical, emotional, and occlusal stress may inhibit the adaptive capacity of the stomatognathic system and make the occurrence of the disorder more likely (8).

Clinical studies agree that chronic medical conditions have strong negative effects on patients quality of life (9, 10).

Main objective of this review was to find a relation between temporomandibular disorder and a decrease in patients quality of life.

Goals of our systematic review:

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Review clinical trials of patients with TMD on international databases to find out about their quality of life.

Find out what methods should be used to determine quality of life of patients with temporomandibular disorder.

Determine why TMD is causing patients to have a lower quality of life.

MATERIAL AND METHODS

A systematic review was conducted which relied on information contained in international databases: National Library of Medicine – Medline/PubMed and Google Scholar.The review was conducted in accordance with PRISMA Statement guidelines. The articles used for this review were found and selected on 6th of February, 2016. The search was conducted with the goal to find clinical trials concerning the relationship between quality of life and temporomandibular disorders. The keywords and their combinations used in our search were: Quality of life, Temporomandibular joint disorders, Temporomandibular dysfunction. A total of two independent investigators performed the aforementioned searches and study selection. The appropriateness of the studies was evaluated by reading and reviewing the articles. The following selection criteria were applied: full text articles, only clinical trials, articles in English, adult patients, selected publications contains information for the tasks specified criteria. Systematic literature reviews and publications considering quality of life as a treatment outcome (related to intervention) are not included in this systematic review.

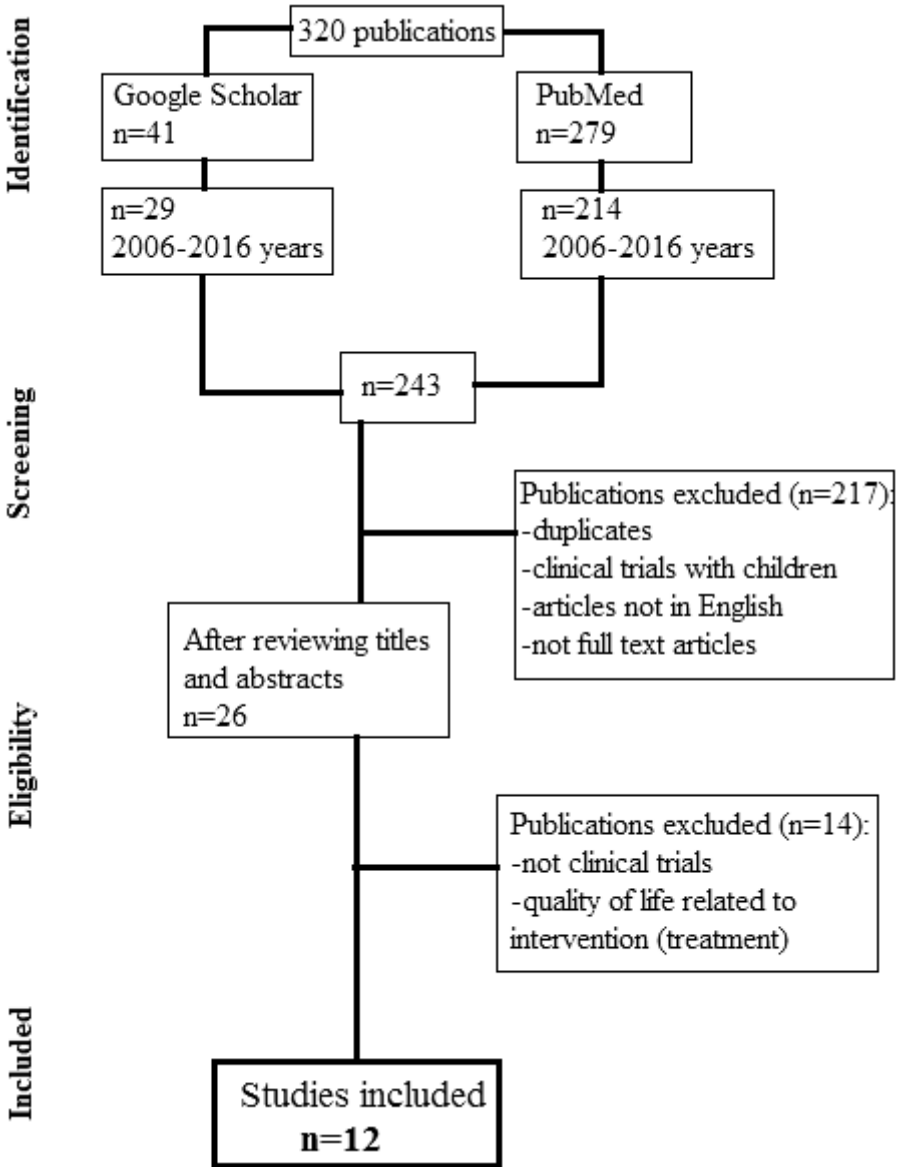

Fig. Search strategy flow chart

A total of 320 publications were initially retrieved. Out of total 320 articles, 41 were found by using Google Scholar and 279 by using PubMed search. Firstly, after initial retrieval, all articles that were older than 10 years were removed, leaving 243 that were suitably up to date. Secondly, article duplicates and incomplete publications were eliminated. The next step of screening involved titles and abstract reviewing. At this stage, the following exclusion criteria were used: duplicates, clinical trials with children, articles not in English, not full text articles. This eliminated most of the articles retrieved from PubMed due to their titles and contents, leaving 26 articles (7 articles from Google Scholar database and 19 articles from PubMed database). Out of 26 remaining studies, 12 were in full accordance with provided inclusion criteria and were included in the systematic review, the 14 that were excluded were either not clinical trials or were related to quality of life after treatment. Due to previous removal of articles older than 10 years our selected publications were published from 2006 to 2016. A total of 12 clinical trials are presented and discussed in the review. Search strategy is illustrated on the flow-chart (Figure).

RESULTS

Relation between quality of life and temporomandibular disorders

The 12 clinical trials that were included in this review, assessed the quality of life of patients with temporomandibular disorders. Three of the selected studies have found that there is a direct relation between temporomandibular disorders and a degradation of patients quality of life (2, 11, 12), however two of the reviewed studies concluded that temporomandibular disorders do not affect the quality of life (13, 14). Another three studies found that patients with this particular pathology have lower quality of life than their control group (4, 15, 16). Finally five studies concluded that more severe cases of TMD disorder, cause lower quality of life (1-3, 7, 17). One of the studies selected pointed out that patients with arthralgia, osteoarthritis or osteoarthrosis have lower quality of life than patients with myofascial pain or disc displacement (3). A brief summary of selected study descriptive characteristics can be found below (Table).

Table. Summary of the study descriptive characteristics of included studies

Research	Quality of life assessment method	Number of patients, gender (average age)	Number of patients in the control group, gender (average age)	Results
Moreno, B. G. D. *et al.* 2009 (15)	SF-36	27 female (30.1±5.8)	18 female (23.4±2.3)	Patients' with TMD quality of life is lower than control group.
Tjakkes, G. H. E. *et al.* 2010 (3)	SF-36 HADS	95 patients, 90 female and 5 male (40.3±13.1)	–	The more severe TMD is, the lower quality of life
Kim, T. Y. *et al.* 2015 (4)	EQ-5D	17, 198 patients (≥19)	–	Patients' with TMD quality of life is lower due to sociodemographic and general health problems
Roberto, D. *et al.* 2009 (16)	SF-36	146 patients, 30 male and 116 female (35, 2 ±14, 38)	–	Patients' with TMD quality of life is lower in all aspects related to pain and depression.
Pereira, T. C. *et al.* 2010 (17)	OHIP-14 QVV	33 female (25.61)	–	The more severe TMD is, the lower quality of life
Gui, M. S. *et al.* 2014 (13)	SF-36	37 female with localized pain (24.92±5.0) and 39 female with widespread pain (53.21±9.34)	40 female (50.93±12.34)	Temporomandibular disorders do not affect the quality of life. Patients' with TMD quality of life in all aspects was the same as in control group.
Rovida, T. A. S. *et al.* 2015 (14)	WHO	39 patients, 2 male and 37 female (38, 7)	–	Temporomandibular disorders do not affect the quality of life, there is no relation between temporomandibular disorders and quality of life
Lemos, G. A. *et al.* 2015 (1)	OHIP-14	135 patients, 58 male and 77 female (18-25)	–	The more severe TMD is, the lower quality of life
Resende, C. M. B. M. d. *et al.* 2013 (11)	WHO	60 patients, 53 female and 7 male (36, 48)	–	There is a relation between temporomandibular disorders and quality of life
Oliveira, L. K. d. *et al.* 2015 (7)	SF-36	119 female	41 female	The more severe TMD is, the lower quality of life
Blanco-Aguilera, A. *Et al.* 2014 (12)	OHIP-14	407 patients, 365 female (42.15 ± 14.63) and 42 male (41.48 ± 17.28)	–	There is a relation between temporomandibular disorders and quality of life
Miettinen, O. 2012 (2)	OHIP-14	149 patients, 79 TMD patients including 18 male and 61 female (43.5±13.1), 70 not TMD patients including 23 male and 47 female (25.3±6.5)	–	There is a relation between temporomandibular disorders and quality of life. The more severe TMD is, the lower quality of life

Methods for assessment of quality of life

The following questionnaires were used to assess mental and physical wellbeing of patients with TMD disorder: SF-36 (3, 7, 13, 15, 16), HADS (3), EQ-5D (4), OHIP-14 (1, 2, 12, 17), QVV (17), WHO (11, 14).

SF-36 – Short Form 36 Medical Outcomes Study questionnaire (used in studies (3, 7, 13, 15, 16)). This self-administrated, general purpose questionnaire is composed of 36 questions related to patients health (16). It is not targeted towards any specific age group, disease or treatment group. The patient has to rate their wellbeing in 8 scales: physical function (10 items), role-physical (4 items), bodily pain (2 items), general health status (5 items), vitality (4 items), social function (2 items), role-emotional (3 items), mental health (5 items) and 1 question comparing evaluation between the current health and their wellbeing the previous year, on a scale from 0 to 100 (higher score meaning better quality of life) (15). Poor average score in any of the 8 scales can be taken as an indication of problems or compromised quality of life (16).

HADS – the Hospital Anxiety and Depression Schedule (3) – this questionnaire is used to evaluate anxiety and depression. It consists of 14 questions, of which odd numbers are used to screen for anxiety (HADS-A) and even numbers for the screening of depression (HADS-D). The patient rates himself on a scale of 0 to 3 on each of the questions. A total score of up to 7 out of 21 in any subscale, indicate a normal quality of life, while 8 and higher may indicate an onset of anxiety or depression (3).

EQ-5D - EuroQol-5 Dimension (4) – composed of 5 segments regarding current health state: mobility (M), self care (SC), usual activities (UA), pain/discomfort (PD), and anxiety/depression (AD). The EQ-5D evaluation questionnaire is only used to assess quality of life. Patient functionality is rated in 3 grades (1 no problem; 2 some/moderate problem; and 3 extreme problem) (4).

OHIP-14 – OHIP-short form questionnaire (1, 2, 12, 17) - questionnaire consists of 14 questions aimed at measuring of patients‘ perception of the impact their oral conditions have on their quality of life. The patient has to rate their wellbeing on a 5-point scale (never – 0, almost never – 1, sometimes – 2, almost always – 3 and always – 4). Final score is obtained by summing obtained values of all 14 questions (17). OHIP-14 consists of 7 segments detailing patients‘ oral health impact on their quality of life: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability and handicap. These segments are based on conceptual model of oral health (2).

QVV – V-RQOL protocol (17) – it is a voice-related quality of life protocol. The purpose of this protocol is to understand how a speech impediment can affect person’s daily activities. It displays a list of possible voice-related issues, to which the individuals has to respond on a 5-point scale, depending on how their voice was affected during the last two weeks (1 – excellent, 2 – very good, 3 – good, 4 – reasonable and 5 – bad). Out of 10 questions in this protocol, 6 of them are for the physical and functional domain and 4 are meant to evaluate patients‘ socio-emotional domain. The full score ranges from 0 (zero) to 100. The higher the value, the lower the quality of life is (17).

WHO – The WHOQOL-BREF – The World Health Organization Quality of Life questionnaire (11, 14) - the questionnaire consists of 2 general questions about the participant’s perception of their quality of life and their health and other 24 questions relating to 4 domains: physical, psychological, social relationships and environment. The patient has to choose out of three available answers, each one rated with a score, depending on the question. After all questions have been answered, the result is summed and converted into scale of 0 to 100. The default scale rating system for severity of the disorder is as follows: without TMD (0 to 15 points), mild TMD (20 to 45 points), moderate TMD (50 to 65) and severe TMD (70-100 points). The scores show a profile of the quality of life of the participants. Higher scores directly correlate to lower quality of life and general patient health (14).

Reasons which determine lower quality of life

The most common symptoms observed in patients with temporomandibular disorders were: chronic pain (3, 4, 7, 12, 15-17); loss of energy (3, 7, 15, 16); activity restriction (inability) of physical ailments and emotional disorders (3, 4, 7, 15-17); emotional state (3, 7, 15-17); general health problems (3, 7, 15, 16); anxiety/depression (2-4, 7, 15-17); taste changes (12, 18), discomfort when eating (12); voice changes (17), absence from work due to chronic pain (19).

The reviewed studies show that 78.13% of patients reported feeling tired or having a sore jaw upon waking in the morning. This leads to a conclusion that poor quality of sleep in TMD patients is important problem because physical and mental health is related to effective sleep which contributes to a good quality of life (19). Some studies noted that

difficulty falling asleep, waking up at dawn and restless or disturbed sleep affected TMD patients (7, 19). 90.62% of the patients complained about squeaks or involuntary clenching of the teeth during sleep. Poor quality of sleep caused by stress and chronic pain leads to impediment in daily, social and family activities, which may result in worse psychological status. This both inhibits their ability to work and minimizes desire to enjoy their free time (19).

DISCUSSION

Last few years have seen increasing growth of interest in oral-health related quality of life. Oral ailments can have consequences that affect various aspects of patients‘ mental and physical wellbeing and impair their quality of life (20). The most common TMD symptom, chronic pain, often leads to various forms of psychological distress like anxiety, stress or depression, social impairment, reduced working capacity, social costs, physical disability, reduced economical income which is caused by extensive need of medical services(21). In worst cases this can lead to unbearable pain or total incapacitation (22). Therefore, it is accepted that quality of life is negatively affected by chronic pain (3). Excluding physical abnormalities of jaw muscles or teeth and joints, emotional stress may also lead most patients to require psychological assistance (22). A large percentage of patients with TMD have reported to have difficulty falling or staying asleep (15). Sleep disruption due to pain is most commonly accented and can lead to sleep apnea and insomnia (19). Furthermore, pain and stress associated with TMD represent a negative influence on systemic health and quality of life, which compromise daily social activities at school or work, social functions, affective and cognitive equilibrium, sleep and physical activities (11).

Although TMD has been mostly observed in adults, epidemiological studies have reported signs and symptoms of temporomandibular disorders in adolescents as well as children (23). The literature review conducted did not cater to either gender, but it should be noted that the number of female clinical trials was higher. To add to that epidemiological studies clearly state that TMD symptoms are more commonly observed in women than men (24, 25). This may have been caused by more female patients with TMD, compared to male, looking for treatment for their pain problems (26). In reviewing gender differences in relation to quality of life, male patients appeared to be more affected by TMD than female (4). On the other hand, some studies show a lower quality of life in women when compared to men with TMD (12, 27).

Out of 12 clinical trials reviewed, 10 (1-4, 7, 11, 12, 15-17) have found a direct relation between worse temporomandibular disorder cases and lower quality of life and general patient health and only 2 (13, 14) did not. This leads to a conclusion that temporomandibular disorder is directly correlated with worse quality of life. Most commonly used methods of assessment were questionnaires SF-36(used in 5 of the clinical trials) and OHIP-14 (used in 4 of the clinical trials).

In summary, it can be reliably concluded that TMD negatively impacts patients quality of life, this is supported by 83.33% of the reviewed clinical trials. Two trials that did not agree with this conclusion (13, 14), had particularly small sample size compared to other clinical trials, this might have been the cause of their different findings. A limitation of this systematic review could have been caused by large female predominance in clinical trials which may have hampered the generalizability of the results.

Only one systematic review about TMD patiens quality of life was found in international databases. So the results of this systematic review were compared to a review about temporomandibular disorders and oral health related quality of life, performed by Dahlström, L. and Carlsson, G. E. in 2010. Clinical trials included in their systematic review were performed between years 1989 and 2009. None of the clinical trials used in 2010 systematic review were used this review. The systematic review performed by Dahlström, L. and Carlsson, G. E. showed that a substantial part of patients with TMD had their quality of life impacted by the disorder. Only about less than 5% of TMD patients experienced no significant impact to their quality of life. In the clinical trials used by this review, most common assessment method used was OHIP-14 questionnaire, it was used in 7 out of 12 reviewed studies. However the review found that gender differences were insignificant and statistically irrelevant in relation to TMD and lower quality of life (20). To summarize, both systematic reviews found direct correlation between lower quality of life and temporomandibular disorder and even after 6 years TMD remains a big problem due to its large influence on patients’ quality of life.

However, in the future, further studies for assessing other factors that impact quality of life (other diseases, social, demographic, psychological factors) are needed to establish and validate the relationship between low quality of life and temporomandibular disorders.

CONCLUSIONS

This systematic review shows, that there is a direct correlation between worse cases or temporomadibular disorder and lower quality of life. Most commonly used methods for quality of life assessment of patients with temporomandibular disorder were: SF-36 and OHIP-14. All questionnaires are equally good in evaluating this topic, but SF-36 and OHIP-14 are short form questionnaires, which are therefore very comfortable to use in everyday practice. It can be concluded that psychological and physical ailments discussed lead to lower quality of life in patients with temporomandibular disorders.

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Received: 28 01 2018
Accepted for publishing: 27 03 2018

Pain Medicine, 21(3), 2020, 613–624
doi: 10.1093/pm/pnz278
Advance Access Publication Date: 29 October 2019
Original Research Article

OXFORD

HEADACHE & FACIAL PAIN SECTION

Effects of Cervico-Mandibular Manual Therapy in Patients with Temporomandibular Pain Disorders and Associated Somatic Tinnitus: A Randomized Clinical Trial

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Disclosure and conflicts of interest: Financial disclosure statements have been obtained, and no conflicts of interest have been reported by the authors or by any individuals in control of the content of this article. No conflicts of interest are declared.

Trial registration: ClinicalTrials.gov, NCT02850055 (http://www.clinicaltrials.gov).

Abstract

Objective. This randomized clinical trial investigated the effects of adding cervico-mandibular manual therapies into an exercise and educational program on clinical outcomes in individuals with tinnitus associated with temporomandibular disorders (TMDs). **Methods**. Sixty-one patients with tinnitus attributed to TMD were randomized into the physiotherapy and manual therapy group or physiotherapy alone group. All patients received six sessions of physiotherapy treatment including cranio-cervical and temporomandibular joint (TMJ) exercises, self-massage, and patient education for a period of one month. Patients allocated to the manual therapy group also received cervico-mandibular manual therapies targeting the TMJ and cervical and masticatory muscles. Primary outcomes included TMD pain intensity and tinnitus severity. Secondary outcomes included tinnitus-related handicap (Tinnitus Handicap Inventory [THI]), TMD-related disability (Craniofacial Pain and Disability Inventory [CF-PDI]), self-rated quality of life (12-item Short Form Health Survey [SF-12]), depressive symptoms (Beck Depression Inventory [BDI-II]), pressure pain thresholds (PPTs), and mandibular range of motion. Patients were assessed at baseline, one week, three months, and six months after intervention by a blinded assessor. **Results**. The adjusted analyses showed better outcomes (all, $P < 0.001$) in the exercise/education plus manual therapy group (large effect sizes) for TMD pain (η 2 $P = 0.153$), tinnitus severity (η 2 $P = 0.233$), THI (η 2 $P = 0.501$), CF-PDI (η 2 $P = 0.395$), BDI-II (η 2 $P = 0.194$), PPTs ($0.363 < \eta$ 2 $P < 0.415$), and range of motion (η 2 $P = 0.350$), but similar changes for the SF-12 ($P = 0.622$, η 2 $P = 0.01$) as the exercise/education alone group. **Conclusions**. This clinical trial found that application of cervico-mandibular manual therapies in combination with exercise and education resulted in better outcomes than application of exercise/education alone in individuals with tinnitus attributed to TMD.

Key Words: Tinnitus; Temporomandibular Pain; Physical Therapy; Manual Therapy; Pain

Introduction

Temporomandibular disorder (TMD) is an umbrella term used to describe a myriad of symptoms including masticatory muscle pain and joint-associated symptoms (degenerative joint disease and capsulitis) [1]. Pain is the most common and limiting feature of TMD, but it can be also accompanied by decreased mobility of the mouth, headaches, stiffness, or fatigue, all of which impact the quality of life of patients. It has been reported that ~75% of the general population will experience TMD-associated symptoms at some point during their life [2]. Köhler et al. [3] found that the prevalence of TMD signs and number of treatments as a result of TMD pain have increased during the last decades. In fact, a recent study observed that orofacial pain and TMD are associated with a substantial burden and impact on society [4].

Another common associated symptom experienced by individuals with TMD is tinnitus. Tinnitus or "ringing in the ears" is described as the subjective perception of sound without any external stimulation [5]. Tinnitus and TMD occur most frequently in the fifth decade of life and are more prevalent in females than in males (female:male ratio = 3:2) [6]. In fact, it has been reported that subjects with TMD are more likely to develop tinnitus than those without TMD [7], and vice versa, people with tinnitus are also more likely to develop TMD-associated symptoms [8]. Tinnitus elicited by the somatosensory system of the temporomandibular joint (TMJ), the masticatory muscles of the neck, is referred to as "somatic tinnitus," which is present in 36–43% of individuals with subjective tinnitus [5].

Physical therapy can be used for the management of TMD-associated symptoms and for somatic tinnitus. Two recent meta-analyses support the use of manual therapy and exercises for TMD pain symptoms; however, no consensus exists on which therapeutic approach is the most effective [9,10]. Similarly, a recent systematic review identified preliminary evidence for physical therapy in the management of subjective tinnitus, although the quality of the identified trials was low [11]. This review included two studies investigating TMJ treatment, for example, occlusal bite splints or adjustments, laser, and jaw exercises [11]. Buergers et al. [12] also reported that patients with TMD-associated tinnitus who received oral splints and physiotherapy experienced positive outcomes; however, no control group was included in this study. To date, no randomized clinical trial has examined the effects of manual therapies targeting the TMJ and cervical spine on individuals with TMD and tinnitus. Therefore, the aim of this clinical trial was to evaluate the effectiveness of adding specific cervico-mandibular manual therapies into an exercise and educational program on clinical outcomes in people with tinnitus associated with TMD. We hypothesized that individuals receiving cervico-mandibular manual therapies in addition to the exercise and educational program will experience better outcomes than those who only receive an exercise and educational program.

Methods

Study Design

A randomized, parallel-group, multicenter clinical trial was conducted to compare the effects of the inclusion of cervico-mandibular manual therapies into an exercise and educational program in patients with tinnitus associated with TMD. The study design was approved by the Institutional Review Board of Universidad Complutense de Madrid, Spain (16/477-E), and the study was prospectively registered (ClinicalTrials.gov: NCT02850055). This report follows the Consolidated Standards of Reporting Trials (CONSORT) extension for clinical trials [13].

Participants

Between January 2017 and December 2017, consecutive patients with tinnitus concomitant with TMD presenting at to one of three private physiotherapy clinics were screened for eligibility criteria. The inclusion criteria were 1) age 18–65 years and 2) diagnosis of tinnitus attributed to TMD; that is, they had to report self-reported tinnitus symptoms and have a diagnosis of TMD according to the Research Diagnostic Criteria for TMD [14]. The following symptoms were assessed using the RDC/TMD criteria: location of pain, jaw range of motion and associated joint pain, clicking sounds, and pain upon muscle and joint palpation. To be considered tinnitus attributed to TMD, an association between both disorders had to be reported by the patient [15]. Most patients associated their tinnitus with TMJ use, for example, during eating.

The exclusion criteria included 1) diagnosis of ear, nose, and throat medical pathology underlying the tinnitus; 2) neurological problems that could potentially cause the tinnitus; 3) inability to read, understand, and complete the questionnaires or understand and follow commands (e.g., illiteracy, dementia, or blindness); 4) comorbid fibromyalgia syndrome; 5) had received physiotherapy or other treatment in the head/neck in the last 12 months; or 6) any contraindication to physical therapy as noted in the patient's Medical Screening Questionnaire (i.e., tumor, fracture, rheumatoid arthritis, osteoporosis, prolonged history of steroid use, etc.). A detailed medical exam including an ear-nose-throat (ENT) exam was performed in all participants. All subjects signed an informed consent before participation in the study.

Randomization and Masking

Once the baseline assessment was completed, patients were randomly assigned to receive either physical therapy plus manual therapy or physical therapy alone.

Concealed allocation was performed by an external researcher not involved in subject recruitment using a computer-generated randomized table of numbers created for each participating site before the beginning of the study. The group assignment was recorded on an index card. This card was folded in half, such that the label with the patient's group assignment was on the inside of the fold. The folded index card was then placed inside the envelope, and the envelope was sealed. A second therapist blinded to the baseline examination findings opened the envelope and proceeded with treatment according to the group assignment.

Treatment Interventions

All interventions were applied by a physical therapist with more than 10 years of experience in the management of patients with TMD. Both groups received six treatment sessions, two sessions the first week and four weekly sessions to complete the treatment in a month, of multimodal physiotherapy treatment of 30 minutes' duration. The intervention included a cranio-cervical and TMJ exercise program, self-massage of the masticatory muscles (masseter and temporalis), and patient education [9,16].

The exercise therapy program consisted of a mixed approach including mobility, postural education, and motor control exercises of the TMJ, the tongue, and the neck; instructions for resting jaw position, head/neck position, and posture were provided [9]. Patients were asked to perform the exercises twice per day during the intervention period. Patients recorded in a diary their adherence to the exercise program during the study period. Therapeutic patient education included a brief description of the neurophysiological mechanism of pain, active coping strategies, distraction strategies, changing behaviors about pain, and correction of inappropriate behaviors of the TMJ, such as tongue parafunctions. All participants received a self-care book for home.

Patients allocated to the cervico-mandibular manual therapy group also received manual therapy techniques focusing on the TMJ and the masticatory and cervical musculature during the treatment sessions. Participants received an oscillatory TMJ inferior glide accessory mobilization of mandible distraction intervention (Figure 1) for 90 seconds. In addition, different manual therapies including pressure release, soft tissue mobilization, or longitudinal strokes of the following cranio-cervical musculature were applied: masseter (Figure 2), temporalis (Figure 3), sternocleidomastoid (Figure 4), and upper trapezius (Figure 5). These muscles were chosen because their pain referral is perceived around the TMJ, the ear, or the orofacial area and can contribute to tinnitus [17–19].

Outcome Measures

All outcomes were assessed at baseline, one week after the treatment program, and three and six months after the last treatment session by an assessor blinded to group allocation.

The primary outcomes were the intensity of TMD (NPRS) and the severity of the tinnitus, assessed by

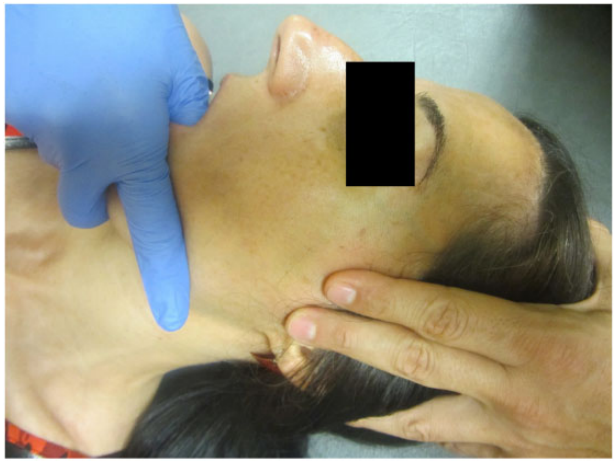

Figure 1. Inferior glide accessory mobilization of the temporomandibular joint.

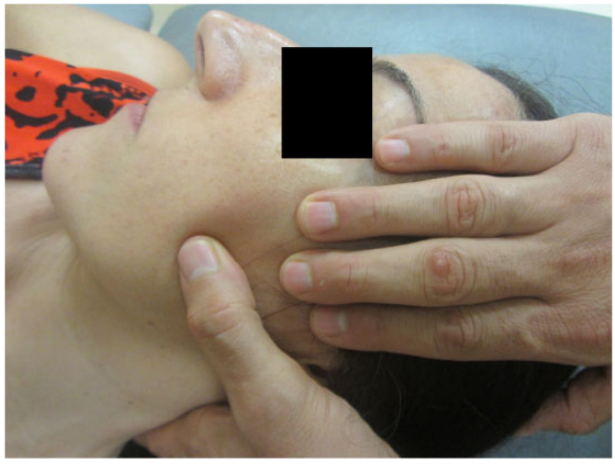

Figure 2. Soft tissue mobilization of the masseter muscle.

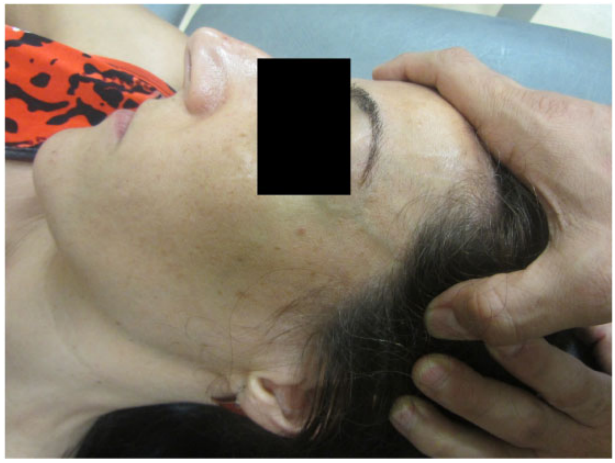

Figure 3. Soft tissue mobilization of the temporalis muscle.

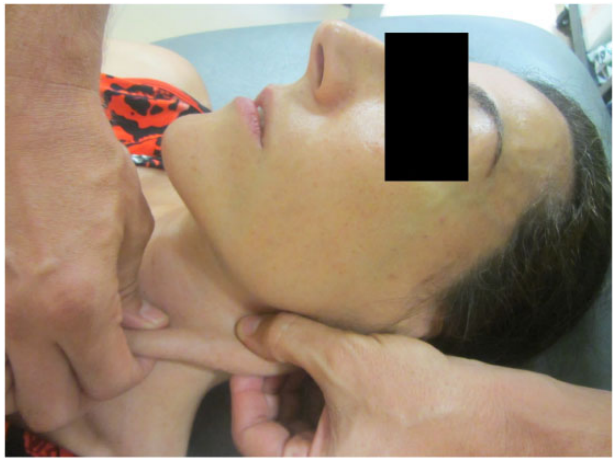

Figure 4. Soft tissue mobilization of the sternocleidomastoid muscle.

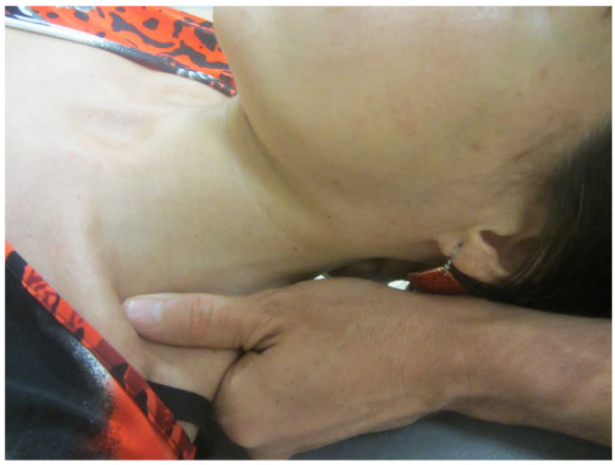

Figure 5. Soft tissue mobilization of the upper trapezius muscle.

tinnitus annoyance and tinnitus loudness (VAS). As patients included in this trial exhibited TMJ pain and tinnitus, both symptoms were assessed separately. Participants rated their intensity of TMD pain at rest on a numerical pain rating scale (NPRS; 0 = no pain, 10 = maximum pain) [20]. As there has not been an identified minimum clinically important difference (MCID) for NPRS in patients with TMD, we set the MCID at a predetermined reduction of two points [21] or a change of 30% of the initial score [22]. The visual analog scale (VAS) was used to assess tinnitus severity (tinnitus annoyance and tinnitus loudness). The VAS scale consisted of a 10-mm line with marked end points with two faces drawn: a smiling one indicating lack of annoyance/no perception of tinnitus (painted under the left end point of a line) and a sad one indicating extreme annoyance or extremely loud tinnitus (painted under the right end point of a line) [23]. The use of a VAS for assessing these subjective symptoms of tinnitus has been shown to have good reliability and validity. The estimated MCID ranged from 10 to 15 mm [23]. It has been also found that the combined VAS of both symptoms is more reliable than the isolated scales; therefore, in the current trial, the mean of both VAS scores was used in the main analysis [23].

Secondary outcomes included tinnitus-related handicap (Tinnitus Handicap Inventory [THI]) [24], TMD-related disability (Craniofacial Pain and Disability Inventory [CF-PDI]) [25], general health-related quality of life (12-item Short Form Health Survey [SF-12]) [26], depressive symptom (Beck Depression Inventory [BDI-II]) [27], pressure pain sensitivity (pressure pain thresholds [PPTs]), and mandibular range of motion.

The THI is a self-reported measure assessing the impact that tinnitus has on daily life and consists of 25 items divided into three scales: functional (11 items), catastrophic (five items), and emotional (nine items) [28]. There are three possible answers to each item: "yes" (four points), "sometimes" (two points), and "no" (0 points). Although each subscale can be scored independently, it has been proposed to report a total score (range = 0–100 points) [29]. Fackrell et al. [30] proposed that a reduction of 20 or more points of the total score of the THI could be considered a clinically meaningful change.

The CF-PDI is a self-administered questionnaire designed to determine pain, disability, and functional status of the mandibular/craniofacial regions [25]. This questionnaire consists of 21 items with a total score ranging from 0 to 63 points, where higher values represent worse functional status. The CF-PDI questionnaire has good internal consistency, reproducibility, and construct validity. It has been reported that a score of 7 can be considered the minimal detectable change for this questionnaire [25].

The 12-item Short Form Health Survey (SF-12) is a generic health rating short version scale of the SF-36 questionnaire [26]. This questionnaire includes 12 questions from the original scales of the SF-36. Response categories for the items vary from two- to six-point scales, and raw scores for items range from 1 to 6. After recoding raw scores for some items, the raw scores are transformed to provide a total score ranging from 0 (the worst health-related quality of life) to 100 (the best health-related quality of life) [26].

Patients completed the BDI-II for reporting their level of depressive symptoms. The BDI-II is 21-item self-report questionnaire assessing different aspects of depression, such as affective, cognitive, and somatic symptoms [27]. The BDI-II is easily adapted in most pain conditions for detecting depressive symptoms [31].

Pressure pain sensitivity was assessed by determining pressure pain thresholds (PPT), that is, the minimal amount of pressure applied on a point for the pressure sensation to first change to pain [32], bilaterally over the masseter and temporalis muscles and over the lateral aspect of the TMJ (anatomical projection of the lateral pterygoid muscle). A digital pressure algometer (kg/cm^2)

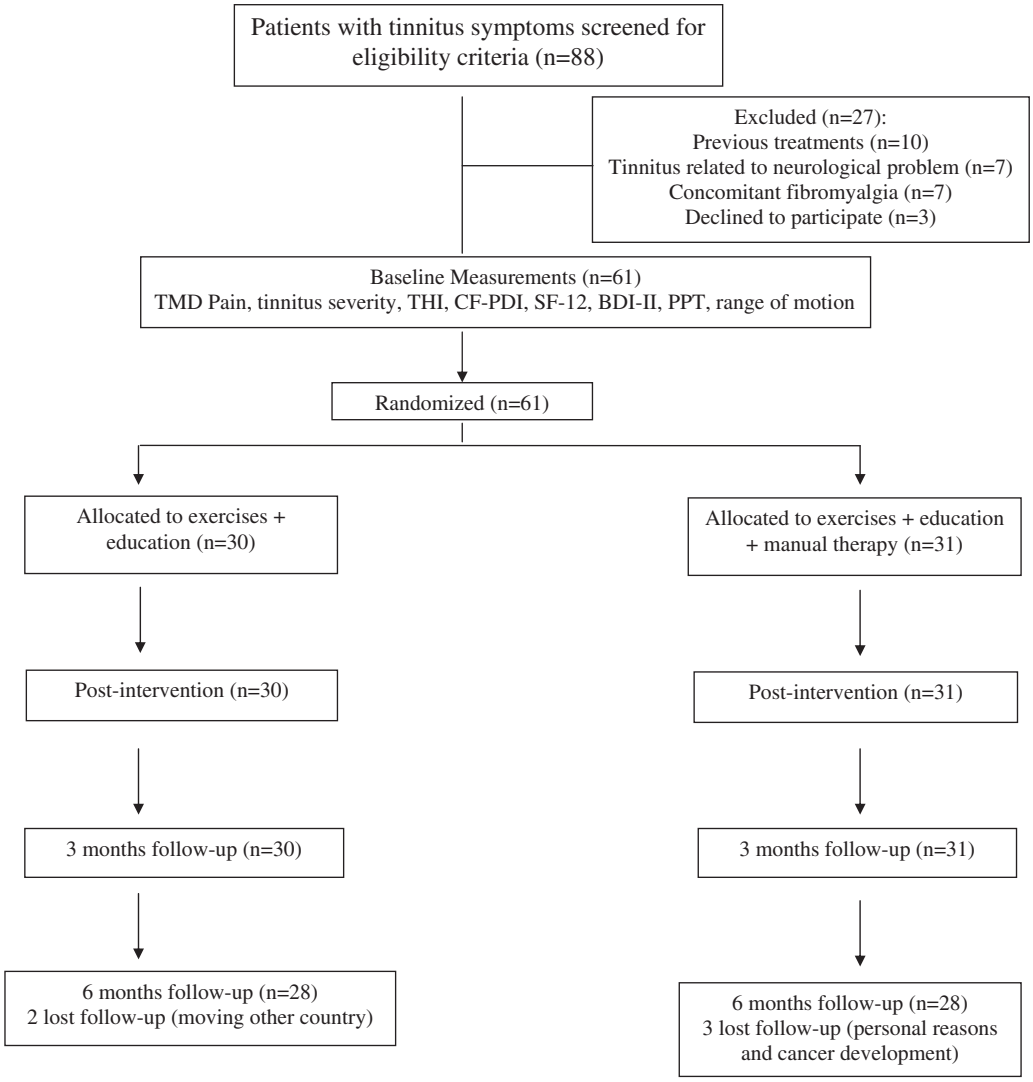

Figure 6. Flow diagram of patients throughout the course of the study.

was used to assess PPTs. All participants were instructed to press the switch when the sensation first changed from pressure to pain. The mean of three trials was calculated on each point and used for the main analysis. A 30-second resting period was allowed between each measure. The reliability of pressure algometry in the masticatory structures has been found to be high in both healthy volunteers [33] and in patients with TMD [34]. As no side-to-side differences were observed, the mean of both sides on each muscle was considered for the analysis. The order of assessment was randomized between subjects.

Mandibular range of motion (maximal mouth opening and lateral excursions) was evaluated with a plastic device permitting the assessment of mouth movements in millimeters. This procedure has exhibited good intra- and inter-rater reliability [35]. The minimal detectable change has been determined to be 6 mm for maximal mouth opening [36] and 1.8 mm for the rest of mouth movements [35].

Treatment Side Effects

Patients were asked to report any adverse event that they experienced during the study. In the current study, an adverse event was defined as sequelae of one week's duration with any symptom perceived as distressing and unacceptable to the patient and that required further treatment [37].

Sample Size Determination

The sample size was calculated using Ene 3.0 software (Autonomic University of Barcelona, Barcelona, Spain). The calculation was based on detecting between-groups differences of 10 mm on the VAS after treatment, assuming a standard deviation of 12 mm [23], a two-tailed test, an alpha level (α) of 0.05, and a desired power (β) of 80%. The estimated desired sample size was calculated to be 25 subjects per group. A dropout rate of 20% was expected, so 30 participants were included on each group at baseline.

Statistical Analysis

Data were analyzed using the SPSS, version 22.0 (SPSS Inc, Chicago, IL, USA), program and were conducted according to the intention-to-treat analysis. Means, standard deviations, and 95% confidence intervals were calculated for each variable. The Kolmogorov-Smirnov test revealed a normal distribution of all quantitative data ($P > 0.005$). Baseline demographic and clinical variables between groups were compared using the independent *t* test for continuous data and chi-square tests of independence for categorical data. A 4×2 analysis of covariance (ANCOVA) with time (before, immediately after, three months after, and six months after) as the within-subjects factor, group (exercise/education alone or exercise/education plus manual therapy) as the between-subjects factor, gender and center as covariates, and adjusted for baseline data was used to examine the effects of interventions on TMD pain, tinnitus severity, THI, CF-PDI, SF-12, BDI-II, PPTs, and mandibular range of motion. Separate ANCOVAs were performed for each outcome. The main hypothesis of interest was the group * time interaction with a Bonferroni-corrected alpha of 0.017 (three moments). The effect size was calculated when the partial Eta squared (η 2 p) was statistically significant. A Partial Eta squared of 0.01 was considered small, 0.06 medium, and 0.14 large [38].

Results

Eighty-eight consecutive subjects with self-reported tinnitus symptoms were screened for potential eligibility between January and December 2017. Sixty-one patients satisfied all criteria, agreed to participate, and were randomly allocated to exercise and education (N = 30) or exercise and education plus manual therapy (N = 31). The reasons for ineligibility are listed in the flow diagram of patient recruitment and retention (Figure 6). Baseline features between groups were similar for all outcomes (Table 1). None of the subjects receiving exercise and education with/without cervico-mandibular manual therapy reported any adverse events. In addition, patients reported an adherence of 97% to the exercise program during the treatment period.

Primary Pain Outcomes

The ANCOVA revealed significant group time * interactions for TMD pain (F = 10.639, $P < 0.001$, η 2 p = 0.153) and tinnitus severity (F = 17.878, $P < 0.001$, η 2 p = 0.233): Patients receiving exercise/education plus manual therapy exhibited a greater decrease (large effect sizes) in both outcomes than those receiving exercise/education alone (Table 2, Figure 7). Gender did not influence the effect in the main analysis (TMD pain: F = 0.509, $P = 0.478$; tinnitus: F = 0.475, $P = 0.493$).

Table 1. Baseline characteristics by treatment assignment

Baseline Variable	Exercise + Education (N = 30)	Exercise + Education + Manual Therapy (N = 31)
Gender (male/female)	13/17	12/19
Age, y	44.0 ± 10.5	42.5 ± 12.0
Months with tinnitus symptoms	17.1 ± 5.0	17.5 ± 6.5
Intensity of TMD pain (NPRS, 0–10)	5.2 ± 1.7	5.2 ± 2.2
Tinnitus severity (VAS, 0–10)	6.7 ± 1.2	6.8 ± 1.2
Tinnitus Handicap Inventory (0–100)	34.2 ± 11.9	36.1 ± 9.5
Craniofacial Pain and Disability Inventory (0–63)	38.6 ± 5.5	40.7 ± 8.2
12-item Short Form Health Survey (0–100)	31.3 ± 3.4	30.0 ± 3.6
Beck Depression Inventory (0–63)	6.5 ± 7.3	7.4 ± 5.4
Mandibular range of motion, mm		
Maximal mouth opening	31.5 ± 3.2	30.5 ± 3.2
Right lateral excursion	5.9 ± 0.7	5.8 ± 0.8
Left lateral excursion	5.9 ± 0.6	5.7 ± 0.7
Pressure pain thresholds, kg/cm2		
Masseter muscle	2.2 ± 0.4	2.1 ± 0.3
Temporalis muscle	2.3 ± 0.4	2.2 ± 0.3
TMJ area	2.2 ± 0.4	2.3 ± 0.4

Data are mean (SD), except for gender.

NPRS = numeric pain rating scale (0–10; lower scores indicate less pain); TMD = temporomandibular disorder; TMJ = temporomandibular joint; VAS = visual analog scale (0–10; lower scores indicate less pain).

Tinnitus and TMD-Related Disability Outcomes

The ANCOVA revealed significant group * time interactions for THI (F = 39.291, $P < 0.001$, η 2 p = 0.501) and CF-PDI (F = 18.096, $P < 0.001$, η 2 p = 0.395): Subjects receiving exercise/education plus manual therapy exhibited greater improvements (large effect sizes) in tinnitus and TMD-related disability than those receiving exercise and education alone (Tables 2 and 3). Gender did not influence the effect in the main analysis (THI: F = 0.142, $P = 0.707$; CF-PDI: F = 0.018, $P = 0.895$).

Health-Related Quality of Life and Depressive Symptoms

The results did not reveal a significant group * time interaction for health-related quality of life (SF-12: F = 0.590, $P = 0.622$, η 2 p = 0.01): Patients in both groups experienced similar changes (small effect size) in quality of life (Table 3). A significant group * time interaction for depressive symptoms (BDI-II: F = 14.234, $P < 0.001$, η 2 p = 0.194) was observed: Individuals receiving exercise and education plus manual therapy exhibited a greater decrease (large effect size) in depressive symptoms than those receiving exercise/education alone (Table 3). Gender did not influence the main effect in the analysis (SF-12: F = 0.586, $P = 0.447$; BDI-II: F = 0.469, $P = 0.496$).

Table 2. Pain intensity and tinnitus outcomes at baseline, postintervention, three months, and six months after treatment, as well as within-group and between-group mean scores by randomized treatment assignment

Outcomes	Timeline Scores, Mean ± SD (95% CI) / Within-Group Change Scores, Mean (95% CI)		Between-Group Differences, Mean (95% CI)
	EX + EDUC	EX + EDUC + MT	
Intensity of TMD Pain (NPRS, 0–10)			
Baseline	5.2 ± 1.7 (4.6 to 5.8)	5.2 ± 2.2 (4.5 to 5.9)	
After intervention	4.1 ± 1.2 (3.6 to 4.6)	3.2 ± 1.8 (2.7 to 3.7)	
Change baseline → after intervention	−1.1 ± 1.0 (−1.6 to −0.6)	−2.0 ± 1.8 (−2.6 to −1.4)	−0.9 (−1.5 to −0.3)*
3 mo	4.0 ± 1.3 (3.4 to 4.6)	2.4 ± 1.8 (1.8 to 3.0)	
Change baseline → 3 mo	−1.2 ± 1.4 (−1.9 to −0.5)	−2.8 ± 1.9 (−3.5 to −2.1)	−1.6 (−2.5 to −0.7)*
6 mo	3.6 ± 1.5 (3.0 to 4.2)	2.2 ± 1.5 (1.6 to 3.0)	
Change baseline → 6 mo	−1.6 ± 1.5 (−2.4 to −0.8)	−3.0 ± 1.8 (−3.7 to −2.3)	−1.4 (−2.2 to −0.6)*
Tinnitus Severity (VAS, 0–10)			
Baseline	6.7 ± 1.2 (6.2 to 7.2)	6.8 ± 1.2 6.3 to 7.3)	
After intervention	5.8 ± 1.2 (5.2 to 6.4)	4.7 ± 1.9 (4.1 to 5.3)	
Change baseline → after intervention	−0.9 ± 1.7 (−1.5 to −0.3)	−2.1 ± 2.0 (−2.9 to −1.3)	−1.2 (−2.0 to −0.4)*
3 mo	5.2 ± 1.5 (4.6 to 5.8)	3.6 ± 1.7 (3.0 to 4.2)	
Change baseline → 3 mo	−1.5 ± 1.9 (−2.2 to −0.8)	−3.2 ± 2.0 (−4.0 to −2.4)	−1.7 (−2.6 to −0.8)*
6 mo	4.7 ± 1.3 (4.2 to 5.2)	2.8 ± 1.7 (2.2 to 3.4)	
Change baseline → 6 mo	−2.0 ± 1.6 (−2.6 to −1.4)	−4.0 ± 2.1 (−4.7 to −3.3)	−2.0 (−3.6 to −1.0)*
Tinnitus Handicap Inventory (0–100)			
Baseline	34.2 ± 11.9 (30.2 to 38.2)	36.1 ± 9.6 (32.2 to 40.0)	
After intervention	29.5 ± 12.2 (25.7 to 33.3)	23.0 ± 8.2 (19.2 to 26.8)	
Change baseline → after intervention	−4.7 ± 7.9 (−7.6 to −1.8)	−13.1 ± 10.4 (−16.9 to −9.3)	−8.4 (−12.8 to −4.0)*
3 mo	28.8 ± 12.3 (25.1 to 32.5)	17.1 ± 7.5 (13.4 to 20.8)	
Change baseline → 3 mo	−5.4 ± 8.1 (−8.4 to −2.4)	−19.0 ± 9.8 (−22.6 to −15.4)	−13.6 (−18.2 to −9.0)*
6 mo	28.3 ± 11.8 (24.7 to 31.9)	14.4 ± 7.3 (10.9 to 17.9)	
Change baseline → 6 mo	−5.9 ± 7.4 (−8.6 to −3.2)	−21.7 ± 8.8 (−25.0 to −18.4)	−15.8 (−19.6 to −12.0)*

ANCOVA = analysis of covariance; CI = confidence interval; EDUC = Education; EX= Exercise; MT= Manual therapy; NPRS = numeric pain rating scale (0–10; lower scores indicate less pain); TMD = temporomandibular disorder; TMJ = temporomandibular joint; VAS = visual analog scale (0–10; lower scores indicate less pain).

*Statistically significant differences between groups (ANCOVA, $P < 0.001$).

Mandibular Range of Motion

The ANCOVA revealed significant group * time interactions for changes in mandibular range of motion (mouth opening: $F = 17.683$, $P < 0.001$, η 2 p = 0.367; lateral excursions: $F = 18.594$, $P < 0.001$, η 2 p = 0.395): Patients receiving exercise/education plus manual therapy exhibited greater increases (large effect sizes) in mandibular range of motion than those receiving exercise and education alone (Table 4). Gender did not influence the interaction effects on maximum mouth opening ($F = 1.083$, $P = 0.302$) or lateral excursions ($F = 0.237$, $P = 0.628$).

Pressure Pain Sensitivity

The ANCOVA revealed significant group * time interactions for changes in PPTs in the masseter ($F = 29.494$, $P < 0.001$, η 2 p = 0.415), temporalis ($F = 18.594$, $P < 0.001$, η 2 p = 0.395), and the TMJ ($F = 15.448$, $P < 0.001$, η 2 p = 0.363): Individuals receiving exercise/education plus manual therapy showed greater increases (large effect sizes) in PPTs (decrease in pressure pain sensitivity) than those receiving exercise/education alone (Table 5). Gender did not influence the interaction effects on PPT (masseter: $F = 0.216$, $P = 0.643$; temporalis: $F = 0.030$, $P = 0.863$; TMJ area: $F = 0.214$, $P = 0.646$).

Discussion

This randomized clinical trial found that inclusion of specific manual therapies targeting the TMJ and the cervical and masticatory musculature into a physical therapy program, including education and exercises, resulted in significantly better outcomes at three and six months than application of education and exercise alone in patients with somatic tinnitus attributed to TMD.

The Clinical Practice Guideline published by the American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF) recommends education and cognitive behavior therapy for the management of tinnitus, but no recommendation of other therapeutic modalities is provided [39]. There is limited evidence for physiotherapy interventions and preliminary evidence for TMJ approaches in patients with somatic tinnitus [11,12]. This clinical trial is the first to add manual therapy targeting the TMJ and the cervical and masticatory muscles into a multimodal approach including exercise and education for patients with somatic tinnitus,

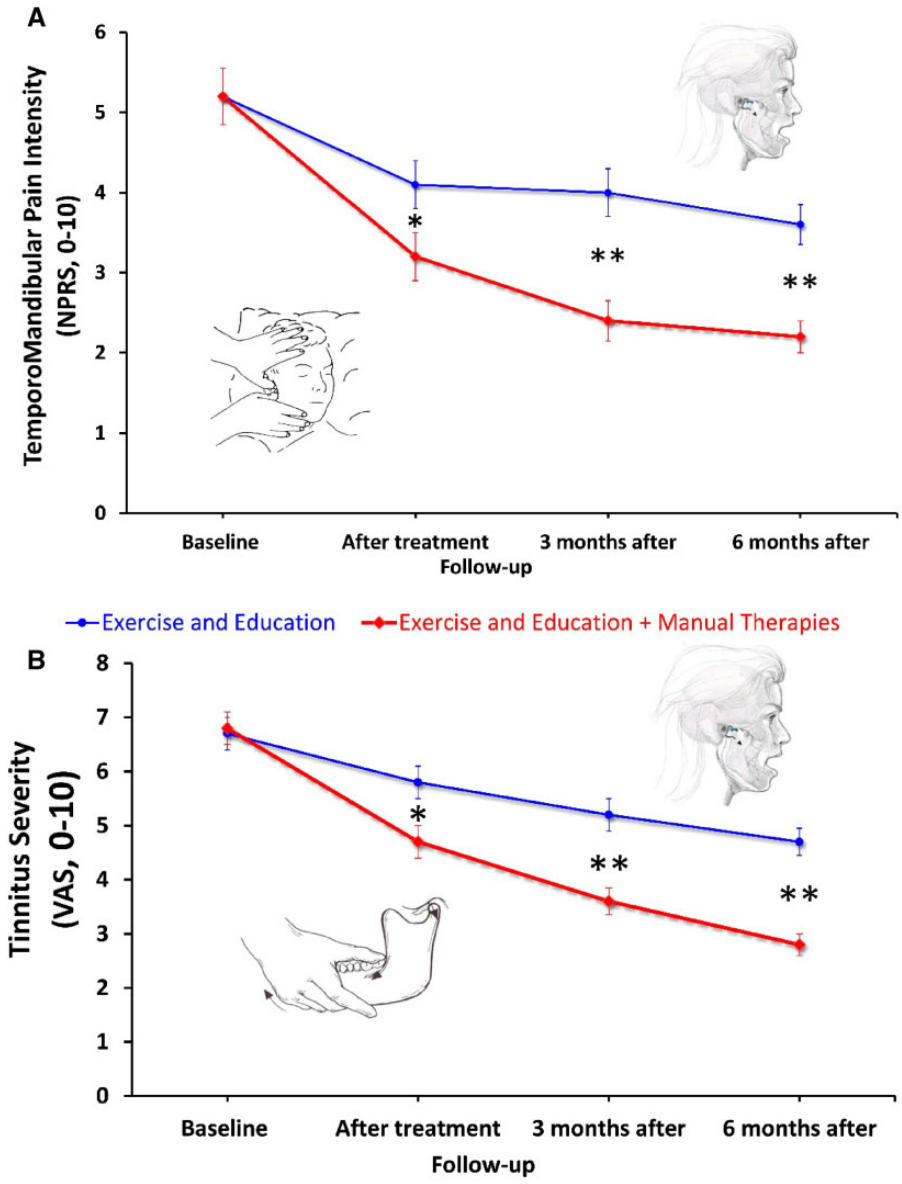

Figure 7. Evolution of temporomandibular pain intensity (A) and tinnitus severity (B) throughout the course of the study, stratified by randomized treatment assignment. Data are presented as mean (standard error). *$P < 0.01$; **$P < 0.001$.

reflecting common clinical practice. The results of our clinical trial found large effect sizes favoring the inclusion of cervico-mandibular manual therapy for the management of people with somatic tinnitus attributed to TMD; however, between-groups change scores did not surpass the MCID for each respective outcome. It should be noted that both groups showed significant within-group improvements in most outcomes, mostly at three and six months; nevertheless, only within-group change scores of the cervico-mandibular manual therapy group surpassed the MCID for most outcomes. Improvements in the physiotherapy group could be related to the fact that exercise and education have been found to be effective for the management of people with TMD symptoms [9,10]. Based on the current results, we could anticipate a potential clinical benefit of adding manual therapy targeting the TMJ and the cervical and masticatory musculature for patients with somatic tinnitus attributed to TMD; however, future trials are needed to clarify the clinical relevance of these therapeutic interventions.

Our results also showed that the inclusion of cervico-mandibular manual therapies was able to induce better improvements in clinical (i.e., tinnitus-related handicap, TMD related-disability), psychological (i.e., depressive symptoms), and physical (i.e., mandibular active range of motion) outcomes, but not in health-related quality of life. These findings suggest that physical therapy approaches for patients with somatic tinnitus should be multimodal by including manual therapy, exercise, and education to facilitate multidimensional improvements in

Table 3. Self-reported secondary outcomes at baseline, postintervention, three months, and six months after treatment, as well as within-group and between-groups mean scores by randomized treatment assignment

	Timeline Scores, Mean ± SD (95% CI)		
	Within-Group Change Scores, Mean (95% CI)		
Outcomes	EX + EDUC	EX + EDUC + MT	Between-Group Differences, Mean (95% CI)
Craniofacial Pain and Disability Inventory (0–63)			
Baseline	38.6 ± 5.5 (6.1 to 7.5)	40.7 ± 8.2 (38.2 to 43.2)	
After intervention	35.2 ± 5.0 (4.0 to 5.6)	33.6 ± 5.0 (31.5 to 35.7)	
Change baseline → after intervention	−3.4 ± 2.1 (−4.2 to −2.6)	−7.1 ± 5.0 (−9.0 to −5.2)	−3.7 (−5.7 to −1.7)*
3 mo	34.0 ± 5.4 (4.1 to 5.7)	29.8 ± 5.8 (27.8 to 31.8)	
Change baseline → 3 mo	−4.6 ± 2.8 (−5.7 to −3.5)	−10.9 ± 5.9 (−13.1 to −8.7)	−6.3 (−8.6 to −4.0)*
6 mo	33.3 ± 5.0 (3.1 to 5.1)	28.7 ± 6.1 (26.7 to 30.7)	
Change baseline → 6 mo	−5.3 ± 2.4 (−6.2 to −4.4)	−12.0 ± 5.0 (−13.8 to −10.2)	−6.7 (−8.7 to −4.7)*
12-Item Short Form Health Survey (0–100)			
Baseline	31.3 ± 3.4 (30.0 to 32.6)	30.0 ± 3.6 (28.7 to 31.3)	
After intervention	31.9 ± 2.2 (30.8 to 33.0)	30.0 ± 3.4 (28.8 to 31.2)	
Change baseline → after intervention	0.6 ± 3.2 (−0.6 to 1.8)	0.0 ± 3.1 (−1.2 to −1.2)	−0.6 (−2.2 to 1.0)
3 mo	32.0 ± 2.5 (31.0 to 33.0)	30.5 ± 2.7 (29.6 to 31.4)	
Change baseline → 3 mo	0.7 ± 3.5 (−0.6 to 2.0)	0.5 ± 4.0 (−1.0 to 2.0)	−0.2 (−2.0 to 1.6)
6 mo	31.9 ± 2.8 (30.9 to 32.9)	30.9 ± 2.4 (29.9 to 31.9)	
Change baseline → 6 mo	0.6 ± 3.6 (−0.7 to 1.9)	0.9 ± 3.9 (−0.5 to 2.3)	0.3 (−1.5 to 2.1)
Beck Depression Inventory (0–63)			
Baseline	6.5 ± 7.3 (4.2 to 8.8)	7.4 ± 5.4 (5.1 to 9.7)	
After intervention	5.7 ± 6.6 (3.6 to 7.8)	4.1 ± 4.9 (2.0 to 6.2)	
Change baseline → after intervention	−0.8 ± 3.3 (−2.0 to 0.4)	−3.3 ± 3.7 (−4.7 to −1.9)	−2.5 (−4.0 to −1.0)*
3 mo	6.3 ± 7.0 (4.2 to 8.4)	3.1 ± 4.6 (1.0 to 5.2)	
Change baseline → 3 mo	−0.2 ± 5.2 (−2.2 to 1.8)	−4.3 ± 3.4 (−5.5 to −3.1)	−4.1 (−6.3 to −2.0)*
6 mo	6.0 ± 7.0 (4.0 to 8.0)	2.4 ± 3.8 (0.4 to 4.4)	
Change baseline → 6 mo	−0.5 ± 5.6 (−2.5 to 1.5)	−5.0 ± 3.8 (−6.4 to −3.6)	−4.5 (−7.0 to −2.0)*

ANCOVA = analysis of covariance; CI = confidence interval; EDUC = Education; EX = Exercise; MT = Manual therapy.
*Statistically significant differences between groups (ANCOVA, $P < 0.001$).

Table 4. Mandibular range of motion at baseline, postintervention, three months, and six months after treatment, as well as within-group and between-groups mean scores by randomized treatment assignment

	Timeline Scores, Mean ± SD (95% CI)		
	Within-Group Change Scores, Mean (95% CI)		
Outcomes	EX + EDUC	EX + EDUC + MT	Between-Group Differences, Mean (95% CI)
Maximum Mouth Opening, mm			
Baseline	31.5 ± 3.2 (30.5 to 32.5)	30.5 ± 3.2 (29.0 to 32.0)	
After intervention	35.0 ± 4.8 (33.5 to 36.5)	39.0 ± 5.0 (37.5 to 40.5)	
Change baseline → after intervention	3.5 ± 2.7 (2.2 to 4.8)	8.5 ± 4.5 (7.3 to 9.7)	5.0 (3.8 to 6.2)*
3 mo	36.0 ± 4.1 (34.5 to 37.5)	41.0 ± 4.5 (39.5 to 42.5)	
Change baseline → 3 mo	4.5 ± 2.6 (3.1 to 5.9)	10.5 ± 3.8 (9.2 to 11.8)	6.0 (5.0 to 7.0)*
6 mo	36.5 ± 4.0 (35.0 to 38.0)	42.0 ± 3.5 (40.5 to 43.5)	
Change baseline → 6 mo	5.0 ± 2.9 (3.6 to 6.4)	11.5 ± 3.3 (10.7 to 12.3)	6.5 (5.0 to 8.0)*
Left Lateral Excursion, mm			
Baseline	5.9 ± 0.7 (5.5 to 6.3)	5.8 ± 0.8 (5.4 to 6.2)	
After intervention	6.5 ± 0.6 (6.3 to 6.7)	7.7 ± 0.7 (7.4 to 8.0)	
Change baseline → after intervention	0.6 ± 0.8 (0.3 to 0.9)	1.9 ± 1.0 (1.6 to 2.2)	1.3 (1.0 to 1.6)*
3 mo	7.0 ± 0.8 (6.6 to 7.4)	8.4 ± 0.8 (8.0 to 8.8)	
Change baseline → 3 mo	1.1 ± 1.0 (0.7 to 1.5)	2.6 ± 0.9 (2.3 to 2.9)	1.5 (1.1 to 2 to 9)*
6 mo	7.2 ± 1.1 (6.7 to 8.2)	9.0 ± 0.8 (8.5 to 9.5)	
Change baseline → 6 mo	1.3 ± 1.1 (1.0 to 1.6)	3.2 ± 0.7 (3.0 to 3.4)	1.9 (1.4 to 2.3)*
Right Lateral Excursion, mm			
Baseline	5.9 ± 0.6 (5.7 to 6.1)	5.7 ± 0.7 (5.5 to 5.9)	
After intervention	6.6 ± 0.7 (6.3 to 6.9)	7.7 ± 0.9 (7.3 to 8.1)	
Change baseline → after intervention	0.7 ± 0.8 (0.4 to 1.0)	2.0 ± 1.1 (1.5 to 2.5)	1.3 (0.9 to 1.7)*
3 mo	7.0 ± 0.7 (6.6 to 7.4)	8.6 ± 1.1 (8.3 to 8.9)	
Change baseline → 3 mo	1.1 ± 1.0 (0.7 to 1.5)	2.9 ± 1.2 (2.4 to 3.4)	1.8 (1.3 to 2.3)*
6 mo	7.2 ± 0.8 (6.8 to 7.6)	9.2 ± 1.0 (8.7 to 9.7)	
Change baseline → 6 mo	1.3 ± 1.0 (0.9 to 1.7)	3.5 ± 1.3 (2.9 to 4.1)	2.2 (1.6 to 2.8)*

ANCOVA = analysis of covariance; CI = confidence interval; EDUC = Education; EX= Exercise; MT= Manual therapy.
*Statistically significant differences between groups (ANCOVA, $P < 0.001$).

Table 5. Pressure pain thresholds (kg/cm^2) at baseline, postintervention, three months, and six months after treatment, as well as within-group and between-groups mean scores by randomized treatment assignment

Outcomes	Timeline Scores, Mean ± SD (95% CI) / Within-Group Change Scores, Mean (95% CI)		Between-Group Differences, Mean (95% CI)
	EX + EDUC	EX + EDUC + MT	
Pressure Pain Thresholds over the Masseter Muscle, kg/cm^2			
Baseline	2.2 ± 0.4 (2.0 to 2.4)	2.1 ± 0.2 (2.0 to 2.2)	
After intervention	2.3 ± 0.5 (2.1 to 2.5)	2.6 ± 0.4 (2.4 to 2.8)	
Change baseline → after intervention	0.1 ± 0.2 (0.0 to 0.2)	0.5 ± 0.3 (0.3 to 0.7)	0.4 (0.2 to 0.6)*
3 mo	2.4 ± 0.4 (2.2 to 2.6)	2.8 ± 0.3 (2.6 to 3.0)	
Change baseline → 3 mo	0.2 ± 0.2 (0 to 1 to 0.3)	0.7 ± 0.4 (0.5 to 0.9)	0.5 (0.3 to 0.7)*
6 mo	2.5 ± 0.4 (2.3 to 2.7)	2.9 ± 0.3 (2.7 to 3.1)	
Change baseline → 6 mo	0.3 ± 0.2 (0.2 to 0.4)	0.8 ± 0.4 (0.6 to 1.0)	0.5 (0.4 to 0.6)*
Pressure Pain Thresholds over the Temporalis Muscle, kg/cm^2			
Baseline	2.3 ± 0.4 (2.1 to 2.5)	2.2 ± 0.3 (2.0 to 2.4)	
After intervention	2.5 ± 0.4 (2.3 to 2.7)	2.6 ± 0.3 (2.4 to 2.8)	
Change baseline → after intervention	0.2 ± 0.2 (0.1 to 0.3)	0.4 ± 0.2 (0.3 to 0.5)	0.2 (0.1 to 0.3)*
3 mo	2.6 ± 0.4 (2.4 to 2.8)	2.8 ± 0.3 (2.6 to 3.0)	
Change baseline → 3 mo	0.3 ± 0.3 (0.1 to 0.5)	0.6 ± 0.2 (0.5 to 0.7)	0.3 (0.2 to 0.4)*
6 mo	2.6 ± 0.4 (2.4 to 2.8)	2.9 ± 0.3 (2.7 to 3.1)	
Change baseline → 6 mo	0.3 ± 0.3 (0.1 to 0.5)	0.7 ± 0.2 (0.6 to 0.8)	0.4 (0.2 to 0.6)*
Pressure Pain Thresholds over the Lateral Aspect of the TMJ, kg/cm^2			
Baseline	2.2 ± 0.4 (2.0 to 2.4)	2.3 ± 0.4 (2.1 to 2.5)	
After intervention	2.4 ± 0.4 (2.2 to 2.6)	2.6 ± 0.3 (2.4 to 2.8)	
Change baseline → after intervention	0.2 ± 0.3 (0.0 to 0.4)	0.3 ± 0.3 (0.1 to 0.5)	0.1 (0.0 to 0.2)
3 mo	2.5 ± 0.4 (2.3 to 2.7)	2.8 ± 0.3 (2.6 to 3.0)	
Change baseline → 3 mo	0.3 ± 0.3 (0.1 to 0.5)	0.5 ± 0.3 (0.3 to 0.5)	0.2 (0.1 to 0.3)*
6 mo	2.6 ± 0.4 (2.4 to 2.8)	2.9 ± 0.3 (2.7 to 3.1)	
Change baseline → 6 mo	0.4 ± 0.3 (0.2 to 0.6)	0.6 ± 0.3 (0.4 to 0.8)	0.2 (0.1 to 0.3)*

ANCOVA = analysis of covariance; CI = confidence interval; EDUC = Education; EX = Exercise; MT = Manual therapy; NPRS = numeric pain rating scale (0–10; lower scores indicate less pain); TMJ = temporomandibular joint; VAS = visual analog scale (0–10; lower scores indicate less pain).

*Statistically significant differences between groups (ANCOVA, $P < 0.001$).

this population. We also observed a localized hypoalgesic effect, as expressed by an increase in PPTs, in both groups, particularly within the manual therapy group. There is evidence supporting that manual therapy is able to increase PPTs in individuals with musculoskeletal pain [40]. These results confirm the neuro-physiological effects of manual therapy and exercise within the central nervous system, as previously suggested [41]. Nevertheless, although changes were superior in individuals receiving manual therapy, between-group differences were small, and clinical relevance remains unclear.

The results of this clinical trial would suggest a correlation between TMD and tinnitus in our sample, as appropriate TMD treatment improved the severity and distress of the tinnitus. The mechanisms linking TMD and tinnitus remain to be further elucidated, and anatomical and physiological theories are currently proposed. For instance, the anatomical relationship between TMJ ligaments and muscles and the inner ear provides a hypothesis regarding where movements of the mandibular condyle producing tension in these structures can result in self-perceived tinnitus. Additionally, different animal studies have described connections between the somatosensory system of the cervical spine and the TMJ and the cochlear nuclei of the ear [42]. Shore et al. [43] showed that the trigeminal and dorsal root ganglia relay afferent somatosensory information from the periphery to secondary sensory neurons within the brain stem, specifically the spinal trigeminal nucleus and dorsal column nuclei, respectively. These physiological links explain that the musculoskeletal somatosensory system of the cervical musculature and TMJ is able to influence the auditory system by altering spontaneous rates (i.e., not driven by auditory stimuli). Any of these hypotheses would explain the results of the current clinical trial, yet they require further scientific evaluation.

The results of this multicenter randomized clinical trial should be considered according to its potential strengths and limitations. Major strengths are the inclusion of patients with defined somatic tinnitus, concealed allocation, a best-evidence multimodal approach treatment including exercise and education, blinded outcome assessments, intention-to-treat analysis, and a six-month follow-up period. Among the limitations, first, as there is no objective method for the diagnosis of tinnitus, this is a self-reported diagnosis; therefore, current data should be not extrapolated to different subgroups of patients. Second, we did not include a control group without application of any intervention, so we do not know the natural course of the disease. It is important to note that

TMDs are often self-limited over time, and significant fluctuation of the symptoms can be observed [44,45]; therefore, we cannot determine if the changes observed in both groups can be specifically attributed to interventions or simply the passage of time. Future clinical trials should include a real control group that does not receive any intervention to determine the real effects of the therapy. Third, the influence of the placebo effect is unknown, as we did not include a group receiving a sham manual therapy approach. We do not know if the facts that patients within the manual therapy group received manual contact and that the clinician spent slightly more time with them could have had a powerful benefit and whether they could have produced the difference between groups. In addition, although we tried to blind patients, it is possible that individuals' expectations for manual contact may also have had an impact on the results. Future trials including a control/sham group should be conducted to determine the best therapeutic option for somatic tinnitus attributed to TMD. Finally, subgroups of patients who would benefit most from these interventions and factors associated with successful treatment in either management approach should be elucidated in future trials.

Conclusions

The inclusion of manual therapies targeting the TMJ and the cervical and masticatory musculature into a multimodal physical therapy program including education and exercise resulted in significantly better clinical, psychological, and physical outcomes at three and six months than the application of education and exercise alone in a sample of patients with somatic tinnitus attributed to TMD.

Authors' Contributions

All authors contributed to the study concept and design. CFdlP, JC, and MJDA did the main statistical analysis and interpretation of data. GPM, CFdlP, and JC contributed to drafting the report. GPM, PMC, and MJDA provided administrative, technical, and material support. PMC and MJDA supervised the study. All authors revised the text for content and have read and approved the final version of the manuscript.

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Evaluation of the Effectiveness of Dry Needling in the Treatment of Myogenous Temporomandibular Joint Disorders

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Abstract: *Background and Objectives*: The objective of our clinical trial was to determine the effectiveness of the deep dry needling technique (DDN) (neuromuscular deprogramming) as a first step in the treatment of temporomandibular disorders. *Methods and Materials*: The double-blind randomized clinical trial comprised 36 patients meeting the inclusion criteria who had signed the corresponding informed consent form. The participants were randomly distributed into two groups, the Experimental group (Group E) and the Control group (Group C). Group E received bilateral DDN on the masseter muscle, while Group C received a simulation of the technique (PN). All the participants were evaluated three times: pre-needling, 10 min post-needling, and through a follow-up evaluation after 15 days. These evaluations included, among other tests: pain evaluation using the Visual Analog Scale (VAS) and bilateral muscle palpation with a pressure algometer; evaluation of the opening pattern and range of the mouth, articular sounds and dental occlusion using T-scans; and electromyography, which was used to evaluate the muscle tone of the masseter muscles, in order to control changes in mandibular position. *Results*: Digital control of occlusion using Tec-Scan (digital occlusion analysis) showed a significant reduction both in the time of posterior disclusion and in the time needed to reach maximum force in an MI position after needling the muscle, which demonstrated that there were variations in the static position and the trajectory of the jaw. The symmetry of the arch while opening and closing the mouth was recovered in a centric relation, with an increase in the opening range of the mouth after the procedure. *Conclusions*: facial pain is significantly reduced and is accompanied by a notable reduction in muscle activity after needling its trigger points.

Keywords: temporomandibular dysfunction; deep dry needling trigger points; myofacial pain; randomized clinical trial

Citation: Dib-Zakkour, J.; Flores-Fraile, J.; Montero-Martin, J.; Dib-Zakkour, S.; Dib-Zaitun, I. Evaluation of the Effectiveness of Dry Needling in the Treatment of Myogenous Temporomandibular Joint Disorders. *Medicina* **2022**, *58*, 256. https://doi.org/10.3390/medicina58020256

Academic Editor: Bruno Chrcanovic

Received: 7 December 2021
Accepted: 4 February 2022
Published: 9 February 2022

1. Background and Objectives

The temporomandibular joint (TMJ), a form of bicondylar diarthrosis that establishes a double connection between the jaw and the temporal bone working symmetrically, is one of the most complex articulations in the body. According to a recent study evaluating historical case series of representative samples of the Spanish population, 12% of adults and elderly patients in Spain experience pain-related symptoms in relation to the muscles of mastication and/or the TMJ [1].

At present, the origin of temporomandibular disorders is considered to be multifactorial, and a series of predisposing or precipitating factors has been described in relation to anatomy, occlusion, parafunction, trauma, and psycho-emotional conditions [2]. These disorders are frequently found to be accompanied by tension-type headaches and other neurological episodes (depression, anxiety) [3]. Furthermore, there is evidence of greater

prevalence in women [4], which seems to be a significant prognostic factor in all the historical case series evaluated in Spain in the latest national surveys on oral health [1].

Multiple therapeutic strategies have been implemented to alleviate the pain and discomfort associated with musculoskeletal pathology in the orofacial area, with different degrees of invasiveness (splints, medications (infiltration of corticosteroids), physiotherapy, regenerative infiltrations (although though the effectiveness of platelet concentrates is at the center of a recent academic debate, since injections of Plasma Rich in Growth Factors or PRGF modulate the inflammatory response and have regenerative activity in damaged joint components of the TMJ), or surgery) [5–10]. Nevertheless, there is still little certainty on the matter. At present, the most consensual approach is to only treat conditions that impact on quality of life through non-invasive means, except when the general repercussions of the clinical presentation worsen, in which case combined and progressively more invasive strategies should be implemented when previous efforts have failed [11].

In this sense, the dry needling technique could be a promising therapy for presentations with chronic muscle involvement (myalgia, referred myofacial pain, or direct myofacial pain) [12]. This minimally invasive technique is based on the insertion of a low-caliber needle, without any additional substances, into myofascial trigger points, which are irritable nodules of a tensed band composed of hypertonic muscle fibers [12]. Two types of dry needling technique exist, based on the depth to which the needle is inserted: superficial needling, or Baldry's Technique, in which the needle is inserted up to the subcutaneous cellular tissue overlying the myofacial trigger point; and deep needling, in which the needle is inserted into the muscle with the intention of reaching the myofacial trigger point [13]. The process behind this technique is the generation of controlled microspasms in the affected muscle area, which alternate with periods of muscle relaxation, with various studies supporting its therapeutic effectiveness [14–16].

In the orofacial area, several authors have studied the effectiveness of dry needling on the muscles of mastication in order to increase the pain threshold to pressure and to maximize the free-of-pain opening of the mouth [17,18]. The study conducted by Luis-Miguel Gonzalez-Perezse et al., focusing on the application of DDN in the lateral pterygoid muscle, which should always be treated under strict ultrasound control due to its complex accessibility and management, reported a reduction in pain and an improvement in maximum mouth opening mobility, jaw protrusion and laterality [18]. This was in agreement with the results obtained in a different DDN study on the temporal and masseter muscles, where the effects measured immediately after and a week after the procedure were evaluated [19]. However, other authors attributed these effects to placebo, although their small sample size (n = 10 per group) could have limited their statistical inference capacity [20,21].

Our study offers an affordable, swift, and easily applicable alternative, which is useful not only as an isolated treatment for muscle dysfunction, but to facilitate or enable the use of other types of intervention carried out by odontologists, such as the reversion to the baseline physiological position of the jaw in centric relation (CR).

The purpose of this study was to evaluate DDN's effectiveness in the treatment of myogenous forms of temporomandibular joint disorder by monitoring the activity of the masseter muscle, bite force, mouth opening range and symmetry, as well as changes in the position of the jaw after applying DDN.

2. Materials and Methods

The sample size necessary to undertake our study was calculated with 95% confidence and 80% statistical power.

We conducted a randomized double-blind clinical trial with a total sample size of 36 patients. Subjects in the sample were recruited from patients attending the Clinical Odontology Consultation of the Faculty of Medicine of the University of Salamanca, as well as university students and other external individuals who wished to participate and met the following inclusion criteria: subjects between the ages of 18 and 40 years, with

myofacial pain due to temporomandibular dysfunction at the time, diagnosed using the Research Diagnostic Criteria (RDC) [21], who had teeth or carried partial fixed prostheses, and showed signs of temporomandibular articular pathology (without determining the degree of TMJ involvement). Patients had not received any other form of treatment related to TMJ disorders.

The exclusion criteria were: a confirmed or suspected diagnosis of an inflammatory disorder (arthralgia), the presence of an oral or dental infection, a confirmed or suspected diagnosis of neurological disorders, a history of physical trauma in the head or face, intake of anticoagulants or drugs for circulation disorders, allergies to metals, and patients with cognitive and/or communication impairments that could hamper necessary data collection [22].

At the beginning of the study, and in order to verify the inclusion criteria, all participants completed a self-administered questionnaire (ANNEX 1) based on the guidelines of the Research Diagnostic Criteria (RDC) for temporomandibular disorders [23].

2.1. Intervention

Each patient was asked to fill in a specific questionnaire on the level of pain suffered before starting the procedure. Pain was evaluated using a visual analog scale, thus allowing the patients to express their own sensation of pain.

The sample was divided into two groups:

Group E: intervention group, who received the deep dry needling technique.

Group C: placebo group, on whom deep dry needling was not performed.

Next, digital occlusal registration was carried out using a T-scan to determine the occlusal contact points, the percentage of occlusal force applied on each tooth, the time needed to reach maximum occlusal force, and the time of posterior disclusion, parameters directly associated with the conditions of the muscles, and which determine postural characteristics at the same time. The electrical activity was registered at baseline and at the maximum intercuspation position (MI) in the masseter muscle after placing the corresponding electrodes in the mandibular angle in parallel to the fibers of the masseter muscle on both sides.

Group E received the DDN treatment in both masseter muscles, using 0.30 × 0.30 mm AGUPUNT acupuncture needles with guides. The technique requires the patient to rest in a supine position, with their eyes closed and with the head rotated towards the right when treating the left masseter muscle and towards the left for the right masseter muscle. The trigger point is identified and marked with a dermographic pen (pain evaluation was carried out through the palpation of different points according to RDC guidelines, using an algometer to determine the exact amount of exerted pressure (ANNEX 3).

The skin was then cleaned and the electromyographic electrodes are placed at the origin and the insertion of the masseter muscle. An antiseptic was subsequently applied on the needling area and the needle was inserted under the aseptic conditions required for the technique. During needling, the physical response of the patient was observed at all times, with the objective of controlling local spasm responses in each masseter muscle Figure 1.

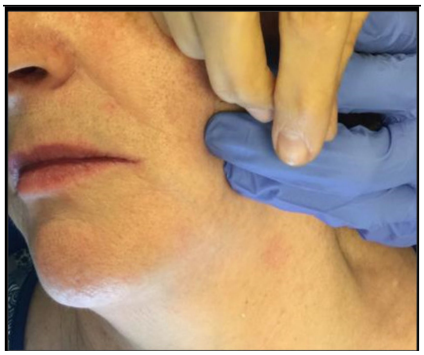

Figure 1. Patient lying in the required position for needling.

Next, the opening pattern and the measurements of the opening of the mouth were evaluated using a digital caliper, and the joint was auscultated on both sides during the opening and closing movements to assess the characteristics of potential sounds (such as clicks, pops, and so on, as well as their volume and frequency) (Figures 2 and 3).

Figure 2. Electromyography surface electrode positioning.

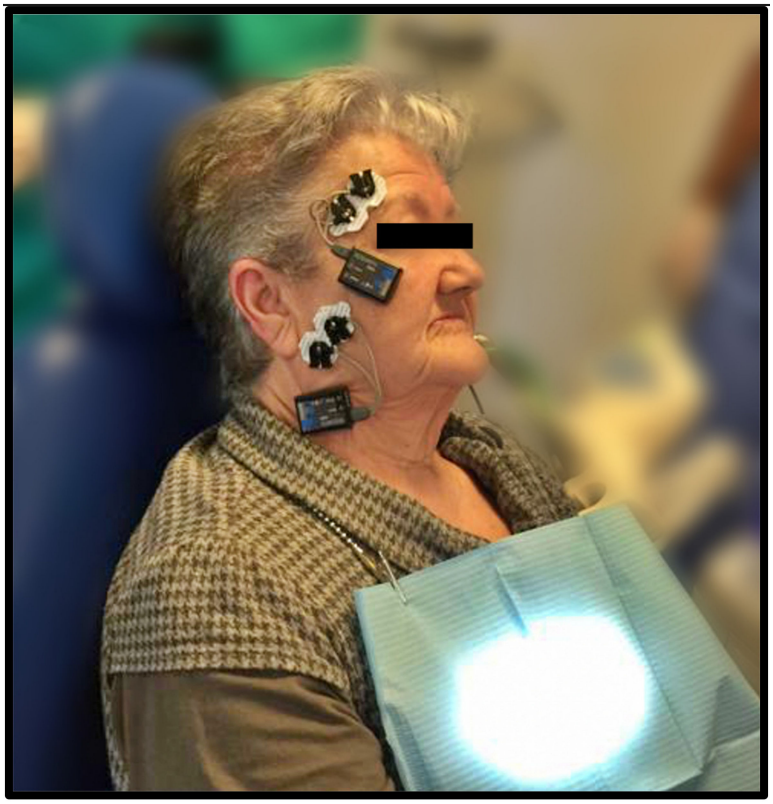

Figure 3. Pre-needling registry of the activity in MI position.

Ten minutes after the procedure, a new evaluation was conducted (post-needling), which included all the above-mentioned change variables.

Group C received a simulation of the DDN treatment. The patient was set in the same position, using the same needle and guide with the same characteristics, and for the same

time as estimated for group E, although in this case the safety piece was not removed so as not to needle the patient. All the aforementioned records were obtained out for muscle activity, mandibular position, mandibular opening and closing patterns, and joint noises, both before and after the simulation of the dry needling maneuver (Figure 4).

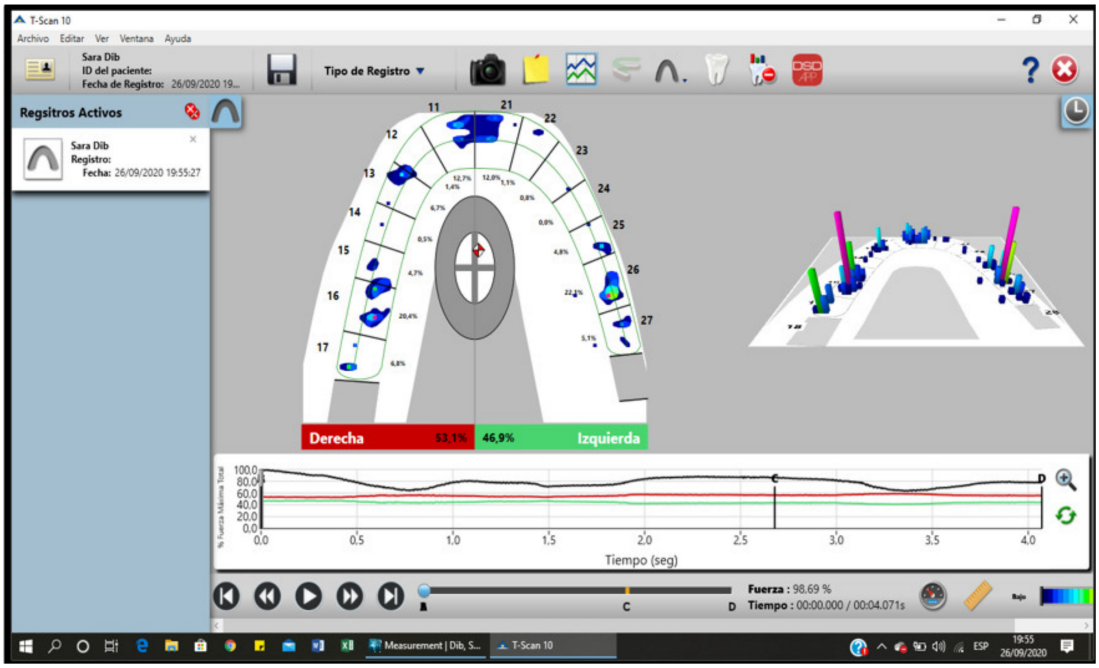

Figure 4. Digital occlusal analysis determining the characteristics of the jaw position.

After conducting the technique, the patient was left to rest for 10 min for the needling to take effect, and afterwards the same evaluation registrations described above were repeated, evaluating the post-needling pain levels. The patient was then asked to fill in the same pain level questionnaire completed at the beginning.

Subsequently, 15 days after the procedure, a new evaluation (follow-up evaluation) was conducted, including, in addition to the change variables registered during the post-needling evaluation, a new, self-administered questionnaire with aspects related to pain and functional activity.

2.2. Data Analysis

The data were analyzed using the IBM.SPSS Statistics program, version 23 and were presented with a 95% confidence level.

3. Results

Table 1 offers the variations of the masseter muscle activity values in both sides, comparing electric activity results during the pre-needling and post-needling phases.

The activity of the same muscle in its maximum intercuspation position was also registered following the same protocol, finding changes in the muscle's electric activity though without statistical significance. These were probably due to the clinical trial's sample size. We registered the following values: 130.73 μV in the right masseter and 125.55 μV in the left masseter pre-needling; and 112.86 μV and 90.71 μV post-needling. The reduction in activity is notable, especially in the left side. This was probably due to prematurity and interferences in the right side, which were evidenced after analyzing the T-scan results. This situation was no longer noticeable in the different CR positions, where the occlusal irregularities that can affect the electric activity of the muscle were nullified.

Table 1. Mean muscle activity value comparison in microvolts (μV) of the masseter muscle in different jaw positions, where RM is relaxed mandible, MI is maximum intercuspation position, CR is jaw in centric relation according to Dawson's bimanual manipulation, CR-L is centric relation measured using Long's laminae, CR-P is centric relation obtained in the position of the first dental contact, DT is jaw disclusion time, P is jaw protrusion position and T-MI is time needed to reach the position of maximum intercuspation. We were able to clearly observe a reduction in activity in the right (19 μV) and left (20.36 μV) masseter muscles in a relaxed jaw position before needling the trigger points. After waiting 10 min post-needling and repeating the same measurement, we obtained values of 23.71 μV/17.65 μV, respectively.

	Mean Pre-		**Deviation Pre-**		**Mean Post-**				**Deviation Post-**			
	Right	**Left**	**Right**	**Left**	**Cont.**		**Interv.**		**Cont.**		**Interv.**	
					Right	**Left**	**Right**	**Left**	**Right**	**Left**	**Right**	**Left**
RM	19	20.36	19.31	25.05	21	15.8	23.71	17.65	20.06	12.76	40.27	18.04
MI	130.73	125.55	227.83	248.22	229	228.75	112.86	90.71	402.1	402.25	222.34	168.37
CR	94	85	73.5	68.38	94	70.50	37.71	34.14	150.70	106.34	58.71	49.14
CR-L	42.91	36.91	66.96	53.86	92	70	30.50	28.3	64.3	52.5	35.3	30.45
CR-P	36.91	33	54.83	46.77	35	30	24.4	20	50.30	40.23	45.5	35.45
DT	3.59		1.74		3.45		2.09		0.5		1.3	
P	94.82	81	147.46	160.41	174.50	98.75	64.57	51.43	255.03	147.54	123.92	87.74
T-MI	0.87		1.21		0.25				0.6			

According to the protocol, regarding the EMG values registered in centric relation positions with different techniques, we found a significant reduction in muscle activity between pre- and post-needling, of > 0.05. Dawson's bimanual technique CR was associated with the highest reduction percentage of the activity of the right 94 μV and left 85 μV muscles before, as well as 31.71 μV right and 34.14 μV left after needling (Figure 5). This striking reduction, corresponding to CR measurement using jaw induction after achieving a relaxed state, is the only technique that does not entail any dental contact, a situation that favors an increase in muscle activity.

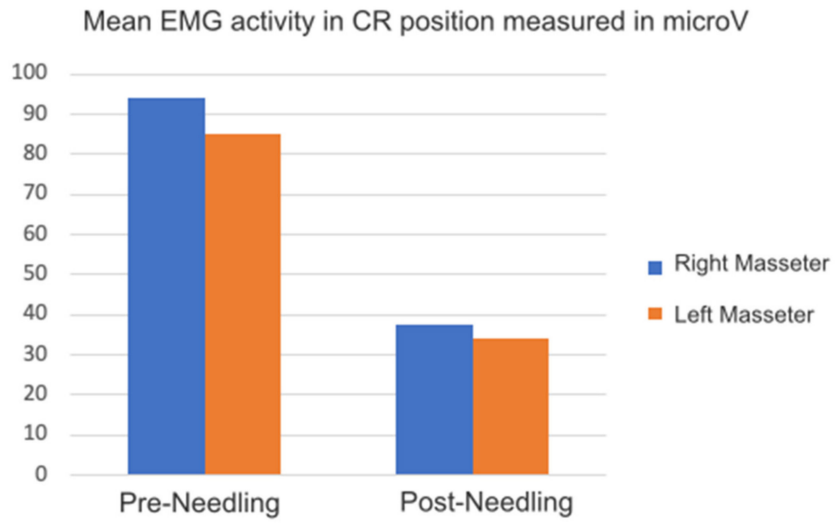

Figure 5. Graph of EMG activity in CR position compared with other techniques (CR-P, CR-L), Table 1.

Considering the EMG, we can sort the methods used for measuring centric relation according to the masseter muscle's activity based on the reduction in EMG activity between the pre- and post-needling states in the following order:

CR according to Dawson's bimanual technique.

CR-P, where centric relation is determined by the closing arch of the jaw up to the first dental contact, with a mean pre-needling activity of 36.91 μV in the right/33 μV in the left masseter and of 24.4 μV in the right/20 μV in the left masseter post-needling.

CR-L, where the centric relation is measured with Long's laminae with a mean pre-needling activity of 42.91 μV in the right/36.91 μV in the left masseter and of 30.5 μV in the right/28.3 μV in the left masseters post-needling.

Figure 6 shows the comparison between the three methods of determining the central relation.

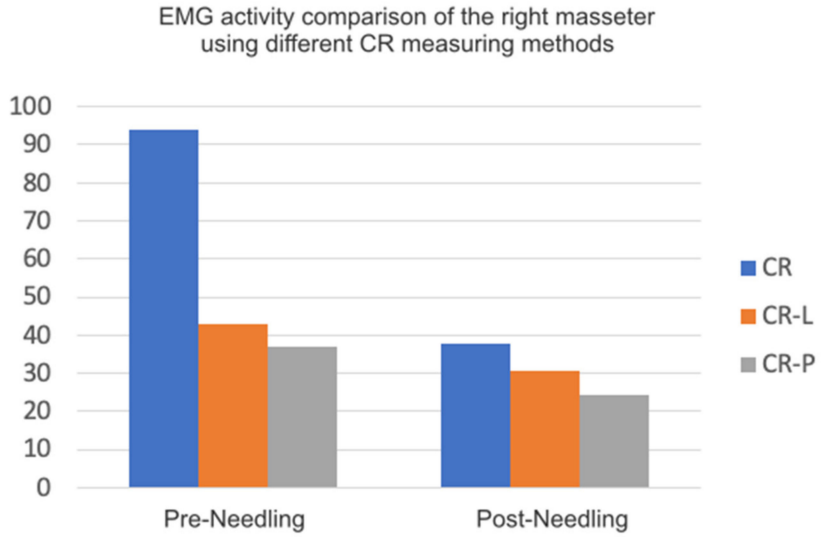

Figure 6. Graph EMG activity comparison of the right masseter using different CR measuring methods. Regarding the opening of the mouth and its symmetry, we found a significant change, of >0.05, in the opening, with a mean value of 44.92 mm pre-needling, measured between the incisal borders of the superior and inferior centrals.

The mean post-needling distance is 51 mm. Figure 7.

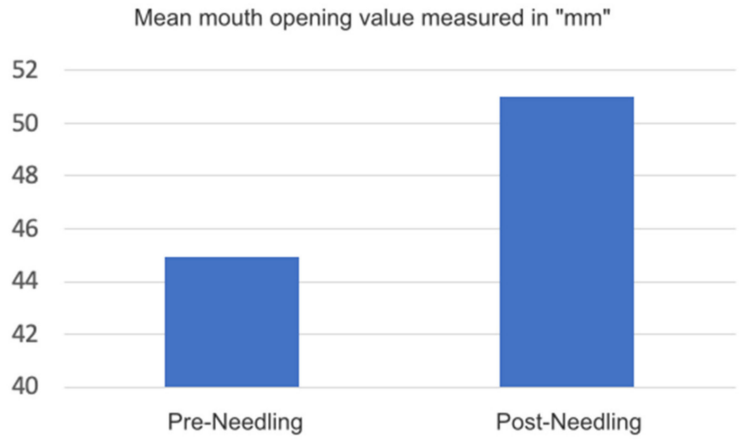

Figure 7. Graph mean mouth opening value measured in mm.

For the symmetry of the arch when opening and closing, we registered significant changes. In certain situations, the symmetry was affected by intra-articular morphological

and structural changes. These modifications where mostly motivated by masseter muscle relaxation after trigger point needling (Table 2).

Table 2. Percentage symmetry of opening and closing mouth.

Presence Percentage	Asymmetry	Symmetry
Pre-	75%	25%
Post-	37.5%	62.5%

For the variable of the time needed to achieve maximum force in a maximum intercuspation position, disregarding the determining factor of the muscle due to the needling technique, and measuring using the T-scan, we found a considerable reduction in the amount of time needed, possibly due to the postural change of the jaw after the procedure, avoiding premature reactions secondary to muscle issues (Figure 8).

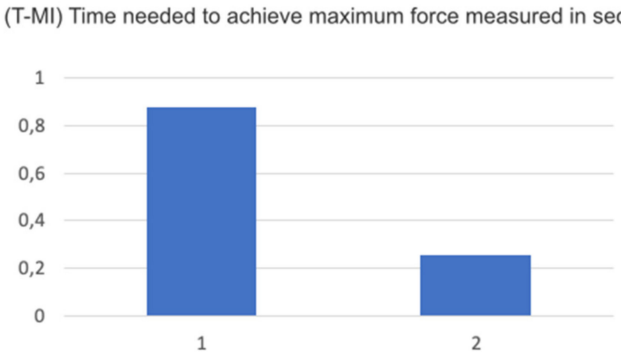

Figure 8. Graph T-Mi, time needed to achieve maximum force measured in seconds.

The posterior disclusion time, a major characteristic of optimal functional occlusion, is usually affected in certain circumstances by the situation of the muscle and vice versa, since delayed posterior disclusion is one of the main reasons for increases in facial pain and EMG activity. According to our results, the reduction in DT was significant: >0.05 (Figure 9).

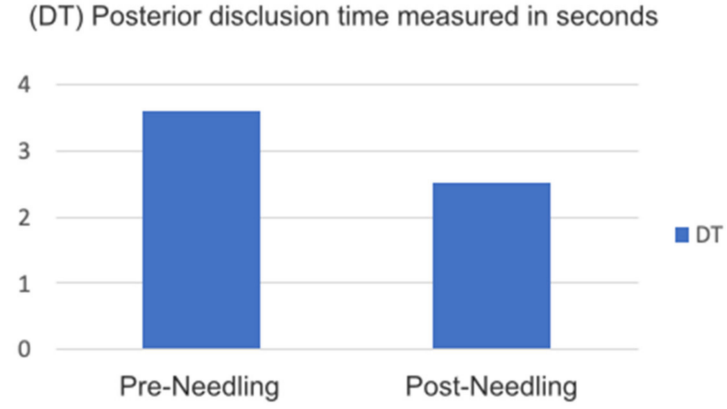

Figure 9. Graph DT posterior disclusion time measured in seconds.

Regarding both articular and facial pain, we registered significant mean values, especially for facial pain, a variable that is directly subject to the state of the muscle. These results are shown in Table 3.

Compared with the results on articular pain measured through VAS in both variables, we observed a smaller reduction in articular pain between the pre- and post-needling states, though intra-articular factors; changes affected this variable more than the effects of the muscle itself.

Table 3. Articular and facial pain.

		Mean Pre-		Dev. Pre-		Mean Post-		Dev. Post-	
		Cont.	**Interv.**	**Cont.**	**Interv.**	**Cont.**	**Interv.**	**Cont.**	**Interv.**
Mouth Opening		44.92		7.36		51.75	51	2.36	2.64
Facial Pain		7.75	8.57	0.95	0.97	0.5	1.5	0.57	0.97
Articular Sound	No	75%	75%			100%	87.5%		
	Yes	25%	25%			0	12.5%		
TMJ pain		2.50	3	1.73	2.77	1	2.63	2	3.24

The articular sounds showed a noticeable improvement at 10 min after needling of the masseter muscle, considering that the muscle factor plays an important role in adjusting the trajectory that the jaw follows in its movement. The results can be found in Figure 10.

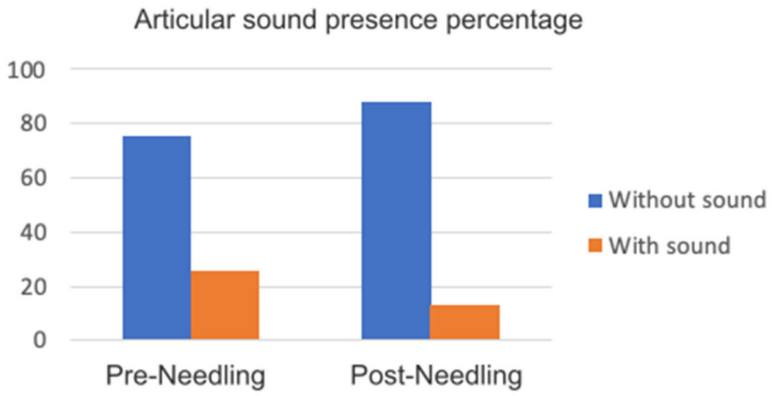

Figure 10. Graph articular sound presence percentage.

4. Discussion

At present, the effectiveness of DDN is more than evident thanks to numerous research studies that have highlighted the importance of ischemic compression and eccentric load in muscle exercises following DDN [21,22].

The first use of DDN therapy was in the 1940s and, since then, numerous studies have tried to analyze this technique in all its diversity. Two meta-analyses comparing the effects of dry needling with wet needling using lidocaine concluded that short-term results are similar [23–26]. In 2016, the Canadian Agency for Drugs and Technologies in Health accepted the use of DDN in the public health system for the treatment of different musculoskeletal pain syndromes [27–30]. A recent meta-analysis study on the use of DDN in temporomandibular disorders concluded that the technique in question considerably reduces pain intensity compared with sham therapy [31,32]. In their meta-analysis, Hall et al. concluded that DDN effectiveness is low at the muscular level, but is higher at the neurological level [33,34].

Gatte et al. proved that DDN effectiveness was low-to-moderate in relation to physiotherapy treatment for musculoskeletal pain in the short- or medium-term [35–39]. Gerwin and Shah proved that DDN is capable of interrupting dysfunction at the terminal of the motor end plate, increasing muscle length and reducing the superposition of actin and myosin fibers [40–42]. Lui Q.G. reports that DDN helps reduce the range and electric frequency at the terminal of the motor end plate, reducing acetylcholine levels [43,44]. Chou and Hsieh report that the spontaneous reduction in electric activity is associated with a cascade of muscle contractions during the DDN procedure [45,46]. This phenomenon leads to a reduction in acetylcholine levels, causing an increase in t blood flow and, in turn, in local oxygenation levels, leading to muscle relaxation in the area [47].

Butts reports that, from a neurophysiological standpoint, DDN reduces both peripheral and central sensitivity by neutralizing nociceptors in the area, modeling de activity of the

dorsal spine through the inhibition of the activity of central pain pathways [48,49]. In their studies, Shah et al proved that with DDN, there is an immediate concentration in the area of neurotransmitters, such as calcitonin, as well as of various cytokines and interleukins, both outside and in cellular fluids [50,51]. Hsieh et al. confirmed that DDN models chemical mediators associated with pain and inflammation by increasing B-endorphins [52,53]. It is evident that DDN cannot be the only therapeutic option when treating chronic pain but must be accompanied by other therapeutic techniques [54,55], such as physical exercise, psychological treatment, and the treatment of sleep disorders [56,57]. Woolf considers that afferent signals and their transmission pathways, as well as nociceptor sensors, constitute the most frequent etiology for myofacial pain [58–60]. Fernández de la Peña reports that trigger points can be considered peripheral sensors for nociception that contribute to pain propagation [61,62]. This theory suggests that the interactions are bi-directional. Their conclusions concur with our results regarding trigger point needling, which deactivates nociceptors, deprograms the affected muscles, and allows mandibular movements free of muscle conditioning [63–66].

Clinically, in situations of chronic pain, a proper understanding by the patient of the mechanism behind the pain is considered crucial [63–65]. Secondly, understanding the role of trigger point needling, its interventions in nociceptors, their pathways, and the effects of the technique on pain relief are also important [66]. Thirdly, the combination of DDN with a good understanding of the mechanism behind its effects is key in reducing kinesiophobia [67,68].

From our point of view, and in light of the results of our study and the duration of DDN effectiveness, we consider the use of the technique as a neuromuscular de-programmer as the first step in the multidisciplinary therapeutic process of myofacial pain.

5. Conclusions

Although, at present, there is no consensus on the effects of DDN, various studies consider that this technique offers swift pain relief despite the short duration of its effects. We observed:

- A significant reduction in facial pain and a reduction in muscle activity after needling trigger points.
- A significant variation in the static position and in the trajectory of the movement of the jaw, determined through digital occlusion control using Tec-Scan (occlusal digital analysis).
- A reduction in the asymmetry of the arch when opening and closing the mouth in the centric relation with an increase in the maximum mouth opening after needling.

Author Contributions: Conceptualization, I.D.-Z. and J.F.-F.; methodology, J.D.-Z. and J.M.-M.; software, S.D.-Z.; validation, I.D.-Z.; formal analysis, J.M.-M.; investigation, J.D.-Z. and S.D.-Z.; resources, J.D.-Z. and J.F.-F.; data curation, J.M.-M.; writing—original draft preparation, J.D.-Z.; writing—review and editing, J.F.-F.; visualization, I.D.-Z.; supervision, J.M.-M.; project administration, J.F.-F. All authors have read and agreed to the published version of the manuscript.

Funding: Expenses arising from the data processing and logistics were borne by Avances en Salud Oral Group (Salamanca, Spain).

Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by the Ethics Committee of University of Salamanca (27 September 2018).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: Not applicable.

Conflicts of Interest: The authors declare not to have any conflict of interest.

Abbreviations

CR	Central relationship
CR-L	Central Relationship through long sheets
CR-P	Central Relationship through the first point of occlusal contact
DDN	Deep dry puncture
DT	Mandibular disclusion time
EMG	Electro-miography
EVA	Visual Analogue scale
MI	Maximum intercuspidation
P	Protrusive position
PP	Placebo puncture
RDC	Research diagnostic criteria
RM	Mandibular rest
TMJ	Temporomandibular joint
T-MI	Time to reach maximum occlusive force
Uv	Micro-volt

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Int. J. Oral Maxillofac. Surg. 2022; 51: 1211–1225
https://doi.org/10.1016/j.ijom.2021.11.009, available online at https://www.sciencedirect.com

International Journal of Oral & Maxillofacial Surgery

Systematic Review
TMJ Disorders

Management of temporomandibular disorders: a rapid review of systematic reviews and guidelines

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C. Tran, K. Ghahreman, C. Huppa, J.E. Gallagher: Management of temporomandibular disorders: a rapid review of systematic reviews and guidelines. Int. J. Oral Maxillofac. Surg. 2022; 51: 1211–1225. © 2021 Published by Elsevier Inc. on behalf of International Association of Oral and Maxillofacial Surgeons.

Abstract. Temporomandibular disorders (TMD) impact a significant proportion of the population. Given the range of management strategies, contemporary care should be evidence-informed for different TMD types. A knowledge-to-action rapid review of systematic reviews published in the past 5 years and guidelines published in the past 10 years concerning the management of TMD was conducted. The Cochrane, Embase, MEDLINE, PEDro, and PubMed databases were searched. A qualitative data analysis was undertaken, with quality assessment completed using the AMSTAR 2 checklist. In total, 62 systematic reviews and nine guidelines considering a range of treatment modalities were included. In concordance with current guidelines, moderate evidence supports a multi-modal conservative approach towards initial management. Contrary to existing guidelines, occlusal splint therapy is not recommended due to a lack of supporting evidence. The evidence surrounding oral and topical pharmacotherapeutics for chronic TMD is low, whilst the evidence supporting injected pharmacotherapeutics is low to moderate. In concordance with current guidelines, moderate quality evidence supports the use of arthrocentesis or arthroscopy for arthrogenous TMD insufficiently managed by conservative measures, and open joint surgery for severe arthrogenous disease. Based on this, a management pathway showing escalation of treatment from conservative to invasive is proposed.

Key words: temporomandibular joint; temporomandibular joint disorders; temporomandibular joint dysfunction syndrome; conservative treatment; surgical specialties.

Accepted for publication 16 November 2021
Available online 23 March 2022

Temporomandibular disorders (TMD) are a group of conditions affecting the temporomandibular joints (TMJ), muscles of mastication, and associated structures. Approximately 5–12% of the global population is affected, with TMD presenting as the second most common musculoskeletal condition to cause pain and disability[1]. Patients with TMD may present with a variety of symptoms including pain, headache, TMJ locking, limited opening, and TMJ noises[2]. A biopsychosocial model of pain is now recognized in the aetiology of TMD, incorporating the cognitive, emotional, and behavioural aspects of pain

perception alongside mechanical initiating factors. These factors may play an important role in influencing treatment decisions and outcomes[3,4].

In 2014, Schiffman et al.[2] developed the Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) for use in clinical and research settings. According to these diagnostic criteria[2], TMD types can be broadly categorized into two groups: pain disorders and joint disorders. The former are typically characterized by regional pain, with the location of the pain enabling a diagnosis of myalgia, arthralgia, or headache attributed to TMD. The latter, joint disorders, are typically characterized by functional limitation. Further assessment can elicit a diagnosis of disc displacement with or without reduction. Finally, findings of crepitus may be indicative of degenerative joint disease.

The Royal College of Surgeons of England (RCSEng) has outlined a wide range of treatments available for the management of TMD[5]. For patients with acute TMD, simple patient education and encouragement of self-management can be employed, alongside several non-invasive therapies. These include physiotherapy, acupuncture, and cognitive behavioural therapy (CBT). A range of hard and soft splints can be provided. Pharmacotherapy, such as non-steroidal anti-inflammatory drugs (NSAIDs), paracetamol, and benzodiazepines, can be prescribed. Local anaesthetic trigger point or botulinum toxin injections can also be administered. For patients with chronic TMD, referral to secondary care is indicated. A patient with TMD may be referred to a specialist in oral medicine, oral surgery, or oral and maxillofacial surgery. In such cases, a range of irreversible therapies may be provided. Occlusal adjustment or prosthodontic reconstruction to manage TMD has been considered. The prescription of tricyclic antidepressants (TCAs) or corticosteroids is available, as well as intra-articular injections of corticosteroid or hyaluronic acid (HA). Surgical interventions are performed on a minority of patients and include arthrocentesis, arthroscopy, eminectomy, eminoplasty, down-fracture of the zygomatic arch, and total joint replacement.

Increasing research into the aetiology, diagnosis, and management of TMD is being performed, driving a change in management ethos from invasive to conservative[6]. To inform evidence-based care, the highest level of scientific evidence can be gained from systematic reviews. These serve to collate, critically appraise, and synthesize relevant primary data on a particular subject. A scoping review by Rinchuse and Greene[6] found that, in PubMed, 110 systematic reviews on TMD had been published as of 2017, compared to only 10 as of 2004. With the latest guidelines on TMD management from RCSEng published in 2013, recent evidence may serve to shed greater light on the most effective management strategies for various TMD types[5].

Against this background, the aim of this rapid review was to evaluate the efficacy of all therapeutic options for the management of TMD by drawing upon recent evidence from systematic reviews and guidelines.

The objective of this review was to investigate the efficacy of different surgical and non-surgical treatment options for the management of TMD.

Methods and design

A knowledge-to-action rapid review evidence summary of systematic reviews and guidelines was undertaken systematically, in line with the methodology developed by Khangura et al.[7]. An unpublished review protocol was written and shared with stakeholders in December 2019.

Systematic reviews considering trials on patients of any age or sex with a clinical and/or radiological diagnosis of any TMD were considered. Participants with two or more types of TMD were included. Systematic reviews of randomized controlled trials (RCTs), non-randomized trials, case series, and case reports were included. Only published systematic reviews and guidelines in the English language were considered for this review. Non-systematic literature reviews were excluded. Only guidelines published in the last 10 years and systematic reviews published in the last 5 years were considered. Where a guideline had been updated, only the latest version was considered.

Any intervention primarily for the management of TMD was considered. These included self-management, physical therapy, psychological therapy, pharmacotherapy, splint therapy, occlusal adjustment, prosthodontic therapy, orthodontic treatment, and surgical therapy.

Any clinical or patient-related outcome measure was considered. These included but were not limited to the following: pain intensity, maximum mouth opening, pain pressure threshold, range of mandibular movement, muscle activity, diet score, recurrence rate, and oral health-related quality of life. Reviews evaluating biochemical or financial outcomes were excluded.

For the identification of articles to be considered for this review, search terms were developed based on subject knowledge and MeSH terms, following consultation with experts in the field. These were applied in search strategies tailored to each database: Cochrane Database of Systematic Reviews, Embase, MEDLINE, PEDro, and PubMed (see **Supplementary Material** Fig. S1). The search results were filtered by publication type for systematic reviews and guidelines only.

The titles and abstracts of all studies were independently and systematically screened by two reviewers (CT and KG). The full texts of remaining articles were assessed for eligibility against explicit inclusion and exclusion criteria, with differences resolved by discussion and input from the wider review team (JEG and CH) where required.

The quality of all included systematic reviews was assessed using the AMSTAR 2 checklist (Assessing the Methodological Quality of Systematic Reviews). Rather than using the checklist to assign each review an overall score, the AMSTAR checklist is designed to allow certain domains greater or lesser weighting in accordance with their overall impact on review quality[8]. Each review was assigned an AMSTAR grading of high, moderate, low, or critically low quality by two reviewers (CT and KG).

Systematic review and guideline details were recorded in a table presenting the characteristics of the included studies. Study characteristics and outcomes data were extracted using a pre-piloted form designed for this purpose. Data were independently extracted by two reviewers (CT and KG). Any disagreements on the above were resolved by discussion with a third author (JEG).

The following data were extracted from systematic reviews: author, publication year, population, intervention, comparison, included studies, results, author conclusions, AMSTAR grade. The following data were extracted from guidelines: author, professional body, publication year, intended setting, recommendations.

Data were analysed qualitatively due to the heterogeneity of the included reviews. Where no systematic reviews published in the last 5 years were found regarding a commonly discussed treatment option, a literature search was conducted to locate the most recent systematic review on this topic.

Results

The initial search yielded 748 articles (577 systematic reviews, 171 guidelines) alongside four additional articles identified

through other sources (one systematic review, three guidelines). The titles and abstracts of 557 articles were screened (425 systematic reviews, 132 guidelines), and the full texts of 94 articles (81 systematic reviews, 13 guidelines) were assessed for eligibility. Twenty-three articles were excluded (19 systematic reviews, four guidelines) for one of the following reasons: did not concern the management of TMD, were not available via King's College London library electronic journal subscription, did not assess clinical or patient-reported outcomes of treatment, involved multiple orofacial pain conditions from which data on patients with TMD alone could not be extracted, did not perform systematic literature search (**Supplementary Material** Appendix 1 and Appendix 2). In total, 71 articles (62 systematic reviews, nine guidelines) were included in the qualitative synthesis. A flow diagram of the article selection process is given in Fig. 1.

Description of included studies

In total, 62 systematic reviews on the management of TMD were identified, assessing self-management (n = 1), conservative management therapies or placebo therapy (n = 3), physical therapies (n = 18), occlusal splint therapy (n = 2), prosthodontic therapy or occlusal adjustment (n = 2), pharmacotherapies (n = 16), and surgical therapies (n = 20). No systematic reviews investigating orthodontic treatment or psychological therapies were found. According to the AMSTAR checklist, three reviews were considered of high quality, 51 of moderate quality, two of low quality, and six of critically low quality. Thirty-eight reviews included only RCTs: the largest included 52 RCTs, whilst the smallest included one. The average number of included RCTs was 13. The remaining 24 reviews included non-randomized controlled trials, prospective or retrospective cohort studies, case series, or case reports alongside any available RCTs. Thirty reviews included meta-analysis. Data extracted from the systematic reviews can be found in the **Supplementary Material** Appendix 3.

Nine guidelines concerning the management of TMD were identified. Six guidelines addressed all treatment modalities for TMD, one guideline focused on pharmacological management, one focused on alternative therapies, and one focused on total replacement of the TMJ. Guidelines were published by RCSEng[5], the National Institute for Health and Care Excellence (NICE)[9,10], the Royal College of Dental Surgeons of Ontario (RCDSO)[11,12], the American Association for Dental Research[13], and the Toward Optimized Practice Headache Working Group[14]. Guidelines were also published following literature review by Rajapakse et al.[15] and Kim et al.[16].

The findings from this literature search have been grouped by treatment modality

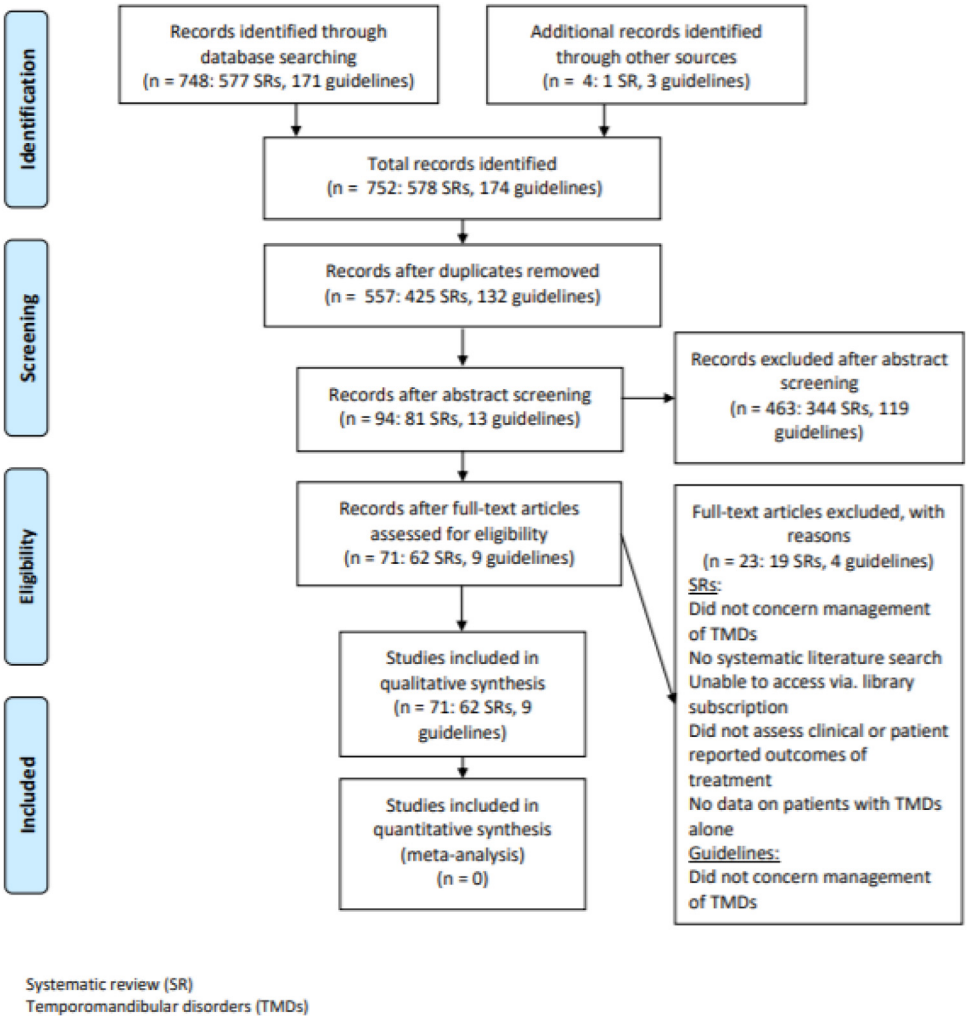

Fig. 1. Study flow diagram showing the identification, screening, and selection of articles.

and reported in order of increasing invasiveness. The recommendations from the guidelines have been described, highlighting any inconsistencies. Against this, the consensus of recent systematic reviews has been outlined. Finally, recommendations for a change in guidance in light of emerging evidence have been made.

Self-management

Two guidelines and one systematic review specifically concern patient-directed management techniques for TMD. Early self-management of symptoms is strongly recommended by RCSEng[5] and NICE[10]. This involves giving reassurance and a clear explanation of the fluctuating nature of TMD, as well as motivating the patient to take responsibility for engaging in self-management techniques. Patients should be encouraged to eat a soft diet, rest the jaw, avoid parafunctional activities, consider the short-term use of simple analgesics, consider localized application of heat or cold, massage the affected muscles, and reduce lifestyle stress[5,10].

One high quality systematic review by Aggarwal et al.[17] comparing self-management for TMD against usual treatment, reported evidence from 11 RCTs on the use of various self-management techniques for chronic TMD, including physical self-regulation, psychosocial self-regulation, and education. Meta-analyses revealed significant improvements in long-term pain and long-term depression with self-management compared to usual care. The authors concluded with high certainty that there was strong evidence to support the use of these self-management techniques for patients with chronic TMD[17].

Against these findings, this review supports the continued recommendation of simple self-management techniques for the initial management of TMD.

Conservative management

Six guidelines and 23 systematic reviews regarding the conservative management of TMD, including physical therapy, psychological therapy, and splint therapy, were identified. Pharmacological therapy was considered separately. Of these, four guidelines and three systematic reviews considered conservative measures collectively, or in general, for the management of TMD.

Alongside self-management, reversible, non-invasive management strategies are recommended as first-line treatment for TMD by RCSEng[5], NICE[10], and RCDSO[11]. These include physical therapies, simple pharmacotherapies, occlusal splint therapy, and psychological interventions. A statement from the American Association for Dental Research[13] strongly supports this approach, recommending conservative, reversible treatment modalities in combination with self-management.

Two moderate quality systematic reviews considered the efficacy of conservative treatment, including physical therapy, CBT, and splint therapy, in managing otological signs and symptoms of TMD. Both reviews acknowledged the limited quality of available evidence, with Stechman-Neto et al.[18] unable to reach definitive conclusions regarding the effect of conservative management on otological signs and symptoms. Michiels et al.[19] concluded there was low quality evidence to suggest that conservative management was beneficial for relieving tinnitus, with a combination of splint therapy and exercise treatment being the most highly investigated approach.

Porporatti et al.[20] conducted a moderate quality systematic review on the effect of the placebo response on TMD-related pain. After qualitative and quantitative analysis of 42 RCTs, the authors concluded that the placebo response may be responsible for 10–75% of pain relief, with laser acupuncture, avocado soya bean extract, and amitriptyline promoting the highest placebo effects.

In summary, the present findings support the continued recommendation of utilizing a range of conservative therapies in the first-line management of TMD.

Physical therapy

Five guidelines and 18 systematic reviews were identified regarding the use of physical therapy. Of these, four guidelines and nine systematic reviews concerned physiotherapies such as exercise therapy, manual therapy, and oral myofunctional therapy. Four guidelines and nine systematic reviews concerned alternative therapies such as acupuncture, transcutaneous electrical nerve stimulation (TENS), and low-level laser therapy (LLLT).

Physical therapeutic interventions aimed at reducing or correcting muscle activity and improving joint function are strongly recommended by RCSEng[5], NICE[10], and RCDSO[11]. Guidelines on primary care management of headache in adults from the Toward Optimized Practice Headache Working Group[14] also recommend a therapeutic exercise programme based on assessment by a therapist or specialist in TMD. RCSEng[5] outlines simple isometric tension and coordination training exercises for self-directed use at home, whilst recommending physiotherapy for certain cases, especially those with cervical muscular pain. NICE[10] recommends referral to physiotherapy if deemed appropriate for advice on passive jaw stretching exercises, posture training, and massage. A recommendation is made by RCSEng[5] on the basis that some short-term benefit may be achieved, especially in acute cases, however symptomatic relief may not be sustained long-term. No technique is recommended, although it is noted that most are exercise-based.

Paco et al.[21] conducted a moderate quality systematic review on the efficacy of physiotherapy, including manual therapy, exercise therapy, and oral myofunctional therapy, for the management of TMD. Meta-analyses revealed significant improvement in pain and active jaw opening with physiotherapy compared to control therapies, although no significant difference in passive jaw opening, range of mandibular movement, or mandibular function impairment questionnaire score was found. The authors concluded that the limited evidence available indicated that physiotherapy interventions were more effective than sham treatment and other treatment modalities for the management of TMD.

The efficacy of exercise therapy for managing TMD was investigated in a moderate quality systematic review by Dickerson et al.[22]. Meta-analysis revealed significant improvement in range of mandibular motion with exercise therapy compared to other interventions of placebo therapy. Improvement in pain and function was also seen, although this did not reach statistical significance.

A moderate quality systematic review on the efficacy of oral myofunctional therapy was conducted by Melis et al.[23]. The authors concluded that with only four low quality RCTs included, the evidence regarding any benefit in pain, otological symptoms, and tenderness of muscles on palpation was low; however oral myofunctional therapy appeared to be effective in managing TMD symptoms.

Against these findings, this review supports the continued recommendation of physical therapies, including oral manual therapy and exercise therapies, for the initial management of TMD.

Manual therapy

Six moderate quality systematic reviews specifically investigating manual therapy for the management of TMD were identified. Whilst one review was unable to

reach a definitive conclusion[24], five reviews agreed that manual therapy was beneficial for managing symptoms of TMD[25–27], with two reviews finding greater efficacy with manual therapy than with other conservative therapies[28,29].

Armijo-Olivo et al.[26] and Calixtre et al.[27] found favourable effects with manual therapy for various outcomes including pain, maximum mouth opening, maximum pain-free opening, and pain pressure threshold of masticatory muscles. However, both found no clear advantage for manual therapy over other management options. This was reflected in the findings from de Melo et al.[24], who were unable to reach conclusive inferences due to the heterogeneity of the data.

Two reviews specifically investigated the effect of manual therapy applied to the cervical spine. Meta-analysis of three RCTs by La Touche et al.[28] found significant pain reduction and improvement in masseter pain pressure threshold in the short term with cervical manual therapy compared to other or no intervention. Case studies reviewed by Adelizzi et al.[25] supported these findings.

Based on these findings, this review supports the continued recommendation of physiotherapy including manual therapy, exercise therapy, and myofunctional therapy for the initial management of TMD as part of a multi-modal, conservative approach. The therapy protocol should be planned on a case-by-case basis by the physiotherapy team.

Alternative therapies

RCDSO[11] outlines a number of alternative therapies that can be undertaken for TMD management by an appropriate healthcare professional. These include acupuncture, TENS, low-intensity laser therapy, and ultrasound therapy. The latter two are recommended on the basis of a potential for pain reduction and improvement in mobility, facilitating engagement with jaw exercises. Based on some supportive evidence for acupuncture in the management of myogenous TMD, RCSEng[5] and NICE[10] recommend directing patients to acupuncture through their general medical practitioner if indicated. Clinical practice guidelines on the use of traditional Korean medicine for TMD recommend the use of acupuncture, laser acupuncture, herbal medicine, manual therapy, exercise therapy, an intra-oral balancing device, and Korean medicine physiotherapy based on low to moderate quality evidence[16].

Zhang et al.[30] conducted a moderate quality systematic review on hypnosis and relaxation therapy for TMD, identifying three low quality RCTs. The authors found a beneficial effect with these interventions for maximum pain and active maximum mouth opening. However, meta-analysis revealed no significant reduction in pain with hypnosis or relaxation therapy compared to no or minimal treatment.

Fertout et al.[31] conducted a critically low quality systematic review on the efficacy of TENS therapy for TMD. The authors found significant improvement from baseline in pain, mouth opening, and inter-occlusal space at rest, although the included studies were not assessed for risk of bias. Despite the low level of evidence available, Fertout et al.[31] concluded that TENS could be considered an effective management option for TMD.

Against these findings, further high quality research evidence of benefit would be required before hypnosis and relaxation therapy or TENS can be recommended for the management of TMD.

Acupuncture and dry needling

A moderate quality systematic review on acupuncture for myogenic TMD was conducted by Tesch et al.[32], including two high quality and two low quality RCTs. Following qualitative synthesis, the authors concluded that significant relief of TMD-related pain with acupuncture was demonstrated with the limited evidence available; however, they suggested that further RCTs were needed before acupuncture can be recommended as an alternative therapy.

Two moderate quality systematic reviews assessed the efficacy of dry needling for TMD of myogenic origin. Meta-analyses in both found a significant increase in pain pressure threshold with dry needling compared to sham therapy, placebo, or other interventions[32,33]. Vier et al.[33] found no significant difference regarding the change in pain intensity and pain-free maximum mouth opening in groups treated with dry needling and sham therapy. However, very low quality evidence showed that dry needling significantly improved pain intensity compared to other interventions in the short term, although the effect size was small. Overall, both authors agreed that dry needling resulted in improved outcomes for myogenic TMD, although strong conclusions could not be drawn[32,33].

Overall, the evidence to support acupuncture for the management of TMD remains limited. Although the present review supports the continued recommendation of acupuncture for TMD before considering more invasive measures on a case-by-case basis, further research is needed before acupuncture can be widely recommended.

Low-level laser therapy

The systematic search identified four systematic reviews on the use of LLLT for TMD. Three moderate quality reviews agreed that based on the limited evidence available, LLLT appeared to be effective for reducing pain and improving function for patients with any TMD type[34–36]. One low quality review concluded that LLLT was not a valid treatment for TMD[37].

Meta-analyses by Xu et al.[36] and Munguia et al.[34] found statistically significant pain reduction with LLLT compared to placebo in the short term, although Xu et al.[36] found this was not reflected at long-term follow-up. In addition, Tuner et al.[35] found that the majority of included clinical trials demonstrated LLLT to be effective for pain reduction compared with placebo.

Meta-analyses by Xu et al.[36] also revealed statistically significant improvement in TMJ function with LLLT compared to placebo, specifically in the domains of maximum active and passive vertical opening and lateral and protrusive excursion. Munguia et al.[34] also found a statistically significant improvement in inter-incisal opening with LLLT at 1 month of follow-up, although this was not seen immediately post-treatment. A minority of clinical trials identified by Tuner et al.[35] showed improvement in mandibular movement with LLLT compared to placebo.

Finally, Doeuk et al.[37] found that six of eight included studies demonstrated LLLT to have a significant beneficial effect; however, due to the limited evidence available they concluded that the management of TMD with LLLT could not be considered valid.

In summary, these findings highlight emerging evidence that alternative therapies such as LLLT may be of some benefit for the management of TMD and should not be disqualified when exploring options for the non-invasive management of symptoms. However, further high quality research is needed before LLLT can be recommended as a treatment option.

Psychological therapy

Three guidelines concerning psychological therapy for TMD were identified. Psychological interventions, particularly CBT, are strongly recommended as initial

management by RCSEng[5] for patients with chronic TMD pain. The recommendation is made on the basis that CBT is a non-invasive treatment that has demonstrated some long-term positive improvement in TMD signs and symptoms. NICE[10] recommends referral to psychology services for CBT in cases of marked psychological distress or pain-related anxiety. Psychological treatment performed by an appropriately trained professional, including CBT, behavioural modification therapy, and mindfulness, is also recommended by RCDSO[11].

The systematic literature search did not identify any systematic reviews concerning psychological therapy for the management of TMD published in the past 5 years. Although later withdrawn, a Cochrane review by Aggarwal et al.[38] concluded that there was weak evidence to support the use of psychosocial interventions for TMD. A later systematic review by Liu et al.[39] regarding CBT in particular, concluded that there was insufficient evidence to strongly recommend this for the management of TMD over other interventions.

In summary, the evidence to support the use of psychological therapies for TMD management is limited. Against these findings, the present review supports the continued recommendation of psychological therapy in cases where underlying psychological factors are thought to play a role in the disease process. However, although simple self-directed therapies may be of benefit, further contemporary research is needed before specialist-led psychological therapies are routinely recommended for the initial management of TMD.

Splint therapy

Three guidelines and two systematic reviews regarding the use of splint therapy for TMD were identified. NICE[10] recommends consideration of night-time use of an occlusal splint for patients with parafunctional habits. RCSEng[5] outlines that splints are provided for TMD patients primarily for providing biofeedback to reduce parafunction and protect dental tissue from wear; however the risk of encouraging hyper-vigilance is also outlined. The Nociceptive Trigeminal Inhibition Tension Suppression System is not routinely recommended by RCSEng[5], except in cases of acute myofascial pain with limited mouth opening, where it may be considered as an emergency appliance. RCDSO[11] cautions against the use of partial coverage appliances due to the risk of overeruption or aspiration.

Two systematic reviews investigating the use of splint therapy for the management of TMD were identified[40,41]. A high quality systematic review of 52 RCTs by Riley et al.[40] compared the use of any splint therapy for TMD with any other therapy. Fifty RCTs were assessed as being at high risk of bias, with the remaining two trials considered to have an unclear risk of bias. Meta-analyses revealed that compared to no treatment or minimal intervention, splint therapy was not associated with any significant improvement in pain, TMJ click, maximum mouth opening, or quality of life at any follow-up period up to 12 months. Similar results regarding improvement in TMJ click and maximum mouth opening were found between groups treated with either splint therapy or control splint, although there was a statistically significant improvement in pain at 0–3 months in the splint therapy group. Overall, the authors concluded that the low quality evidence available provided no suggestion that splints improved any outcomes associated with TMD.

A moderate quality systematic review by Nagori et al.[41] compared the use of postoperative splint therapy after arthrocentesis against arthrocentesis alone. The authors concluded that there was weak evidence to suggest that splint therapy may not improve outcomes after arthrocentesis.

In summary, the above evidence finds that there is no clear evidence to support the use of occlusal splints in the management of TMD. Therefore, unless strong evidence of the efficacy of occlusal splints emerges, the present review recommends that in contrast to current guidance, occlusal splint therapy should not be used in the routine management of TMD.

Prosthodontic or occlusal treatment

Two guidelines and two systematic reviews concerning prosthodontic therapy or occlusal adjustment for TMD were identified. Although NICE[10] guidelines recommend consideration of referral to a dentist if suspected malocclusion or a dental pathology is thought to be associated with TMD, RCSEng[5] states that there is no evidence to support occlusal adjustment for the management of TMD. Certain exceptional cases are outlined, including adjustment of an acute occlusal change causing new TMD symptoms, extraction of a tooth to allow fitting of an occlusal splint, and minor adjustment of occlusal interferences after successful treatment with a stabilization splint. Prosthodontic reconstruction is not recommended as primary treatment for TMD due to the lack of supporting evidence.

Two critically low quality systematic reviews on prosthodontic or occlusal treatment for TMD were found. In both reviews, no studies were found that fully satisfied the inclusion criteria. Both authors therefore concluded that due to the lack of evidence to support the use of prosthodontic or occlusal treatment for TMD, these are not acceptable as management strategies[42,43].

Given these findings, this review supports the continued recommendation against the routine use of prosthodontic therapy or occlusal adjustment for the management of TMD.

Orthodontic treatment

Both RCSEng[5] and RCDSO[11] do not recommend the use of orthodontic treatment to manage TMD due to the lack of evidence to support its efficacy.

The systematic literature search did not identify any systematic reviews concerning orthodontic treatment for the management of TMD published in the past 5 years. A systematic review by Luther et al.[44] on this subject found no relevant studies for inclusion, therefore the authors concluded that there was insufficient evidence to support this practice.

Against this finding, this review supports the continued recommendation against the use of orthodontic treatment for the management of TMD.

Pharmacotherapy

Three guidelines and 16 systematic reviews concerning pharmacotherapy for TMD were identified. Of these, three systematic reviews concerned topical or oral pharmacotherapeutics, six concerned intra-articular injections, and seven concerned intra-muscular injections.

For the primary care setting, RCSEng[5] and NICE[10] recommend short courses of NSAIDs such as ibuprofen used in a stepwise manner, with paracetamol for pain relief in acute onset TMD. Short courses of topical treatments, including ibuprofen gel, are also recommended for myofascial TMD. Both guidelines also recommend the short-term use of benzodiazepines, such as diazepam, for the relief of acute myogenous TMD with limited opening.

For further management of chronic TMD, RCSEng[5] outlines a number of pharmacological interventions currently used. However, the evidence to support

their use is far below the standard required for validated clinical practice, therefore the majority of pharmacotherapeutics are used unlicensed for TMD. Low-dose TCAs may be used for chronic TMD unmanaged by conservative therapy. Gabapentin may be used for myofascial TMD, and propranolol may be used for myofascial TMD with or without arthralgia. These medications are also outlined in guidance from RCDSO[11,12], with the additional recommendation of muscle relaxants such as cyclobenzaprine, orphenadrine, tizanidine, or methocarbamol for myofascial pain related to nocturnal parafunction. The guidelines caution that opioids are rarely indicated[12].

Häggman-Henrikson et al.[45] conducted a moderate quality systematic review on the efficacy of any pharmacological treatment for the management of adults with chronic TMD. Twenty-four RCTs on patients with arthrogenic and myogenic TMD were included, comparing a number of pharmacotherapies including NSAIDs, propranolol, cyclobenzaprine, clonazepam, granisetron, intra-articular sodium hyaluronate or corticosteroid, intra-muscular botulinum toxin, and topical 'Ping-On'. The qualitative synthesis suggested that NSAIDs and intra-articular injection of corticosteroid or hyaluronate were effective for the relief of pain from arthrogenic TMD. Cyclobenzaprine also appeared to provide effective pain relief for myogenic TMD. However, the evidence was limited due to the small number of available studies on each drug.

A moderate quality systematic review comparing the use of NSAIDs with any other conservative therapy was conducted by Kulkarni et al.[46]. Eleven RCTs were identified, evaluating a number of NSAIDs including ibuprofen, topical and oral diclofenac sodium, naproxen, and celecoxib. Following qualitative synthesis, the authors concluded that there was some evidence to suggest that NSAIDs are beneficial for relieving pain and improving mouth opening in patients with TMD. Topical administration appeared to show similar efficacy to oral administration without the risk of gastrointestinal side effects. However, there was insufficient evidence to identify the optimal type, dosage, and duration of NSAID for the management of TMD.

Melo et al.[47] conducted a moderate quality systematic review on the use of oral glucosamine supplements for the management TMJ osteoarthritis. The qualitative synthesis of three RCTs revealed comparable efficacy of glucosamine supplements with ibuprofen at 12 weeks, however no advantage over placebo at 6 weeks. Due to the low level of evidence available, the authors advised that findings must be interpreted with caution.

No systematic reviews published in the last 5 years regarding the use of TCAs was found. The most recent review on this topic identified was published in 2009. The authors concluded that there was weak evidence in favour of using TCAs for the management of TMD; however, further high quality research was needed[48].

Based on these findings, this review supports the continued recommendation of simple analgesics, including paracetamol and ibuprofen, for the initial management of both myogenous and arthrogenous TMD as part of a multi-modal, conservative approach. Further research regarding the efficacy of TCAs, benzodiazepines, and other muscle relaxants is needed before recommendations can be made.

Intra-articular injection

According to RCSEng[5] guidelines, intra-articular corticosteroid injection can be used to manage inflammation in arthritic TMD. However, the College warns that the efficacy of corticosteroid injection is unclear, and use should be limited due to the risk of condylar lysis. The guidelines also outline the use of intra-articular HA for TMJ osteoarthritis, although the evidence to support this remains low.

Five moderate quality systematic reviews investigated the efficacy of intra-articular injection of corticosteroid or HA, either alone or in combination with arthrocentesis. Reviews included RCTs on the management of patients with TMJ osteoarthritis, rheumatoid arthritis, and internal derangement.

Liu et al.[49] compared patients treated with combined arthrocentesis and corticosteroid injection and arthrocentesis alone. No significant difference was found between the groups in terms of pain intensity and maximum incisal opening in the short term; however significant improvements in these outcomes were found in the corticosteroid group at long-term follow-up. No clear consensus was found by Davoudi et al.[50], with the authors concluding that corticosteroid use during arthrocentesis showed no clear superiority over other treatment regimes.

When comparing patients treated with sodium hyaluronate injection to patients receiving placebo therapy, Moldez et al.[51] found no significant difference in the number of patients with a reported improvement in symptoms, although there was a significant improvement in mandibular function with sodium hyaluronate. A qualitative synthesis by Ferreira et al.[52] showed some efficacy in pain relief with HA injection, although there was no clear advantage for combined arthrocentesis and HA over arthrocentesis alone.

Meta-analyses by Liu et al.[49] and Moldez et al.[51] found no significant difference between the groups treated with intra-articular corticosteroid versus HA in terms of reduction in pain intensity, improvement in maximum mouth opening, and number of patients with a reported improvement in symptoms. These findings were supported by the qualitative synthesis of Goiato et al.[53], although Ferreira et al.[52] found mixed results. No significant difference between groups was found regarding the incidence of adverse events[49].

Overall, all five reviews agreed that the level of available evidence was low and lacking in consensus on the management of arthrogenous TMD including TMJ osteoarthritis, rheumatoid arthritis, and internal derangement. Two reviews concluded that corticosteroid injection offered no clear advantage over other therapeutic drugs during arthrocentesis[50], although Liu et al.[49] found corticosteroid injection alone appeared to be effective for long-term symptomatic relief. Three reviews concluded that the use of HA alone appeared to provide some benefit for symptomatic relief of arthrogenic TMD[51–53]; however HA combined with arthrocentesis was not superior to arthrocentesis alone[52]. No clear difference in efficacy was found between the use of HA and corticosteroid[49,51,53].

Nagori et al.[54] conducted a moderate quality systematic review on the use of dextrose prolotherapy for the management of TMJ hypermobility. Meta-analysis of three RCTs showed significant improvement in pain intensity with dextrose prolotherapy compared to placebo, however no significant difference in maximum mouth opening or frequency of luxation was seen between the groups. The authors were unable to reach definitive conclusions due to the limited amount of available evidence.

In summary, the findings of the present review support the use of intra-articular HA injection for the management of arthrogenic TMD including TMJ osteoarthritis, rheumatoid arthritis, and internal derangement. Corticosteroid injection should be considered with caution on a case-by-case basis if more conservative measures have failed. Further research on dextrose prolotherapy for the management of TMJ hypermobility must be con-

ducted before recommendations can be made.

Intramuscular injection

RCSEng[5] outlines the use of intra-muscular injection of local anaesthetic of botulinum toxin for TMD, particularly for recurrent dislocation. However, the evidence to support these treatments was low. More recent guidelines from RCDSO[11] recommend the use of botulinum toxin for myospasm or muscle hyperactivity-related myalgia when conservative treatments fail to resolve symptoms.

Six systematic reviews comparing the use of intra-muscular botulinum toxin injection with other interventions, placebo, or no intervention were found. One review was considered high quality, two were moderate quality, one was low quality, and two were critically low quality. The majority of reviews focused on TMD of myofascial origin.

Meta-analysis by Machado et al.[55] revealed significant improvement in pain intensity with botulinum toxin injection compared to placebo at 1 month, although this was not seen at 3 or 6 months. Findings of Patel et al.[56] appear to support this, with the majority of included studies reporting greater pain reduction in botulinum toxin groups than control groups. However, the qualitative synthesis by Awan et al.[57], Chen et al.[58], and Thambar et al.[59] showed a lack of clear consensus regarding the efficacy of botulinum toxin for pain reduction. Serrera-Figallo et al.[60] included one RCT in their systematic review. Effective pain reduction was found with both botulinum toxin and LLLT, although the effect was greater with LLLT.

Meta-analysis by Machado et al.[55] found no significant difference in maximum mouth opening between groups treated with botulinum toxin injection compared to placebo groups. The qualitative syntheses by Patel et al.[56] and Chen et al.[58] appear largely to support this. However, findings regarding maximum mouth opening by Awan et al.[57] and Thambar et al.[59] are largely equivocal, with no clear consensus shown.

Overall, four reviews were equivocal or unable to reach definitive conclusions[55,57–59], whilst Patel et al.[56] and Serrera-Figallo et al.[60] supported the use of botulinum toxin for TMD of myofascial origin.

Machado et al.[61] conducted a moderate quality systematic review on the use of dry or wet needling, involving intra-muscular injection of local anaesthetic, botulinum toxin, corticosteroids, or other drugs for myofascial pain. The authors concluded that although dry needling and local anaesthetic injection appeared to show some benefit regarding pain relief and improvement in maximum mouth opening, definitive conclusions could not be drawn due to the poor quality of evidence available.

In summary, against these findings, the present review supports the continued recommendation of considering intra-muscular botulinum toxin for cases of myospasm or muscle hyperactivity-related myalgia when more conservative treatments fail.

Surgical therapy

Three guidelines and 21 systematic reviews concerning the surgical management of TMD were identified. Of these, one considered orthognathic surgery, six considered minimally invasive surgery for joint disorders, three considered platelet-rich plasma (PRP) injection for TMJ osteoarthritis, three considered the management of TMJ luxation, four considered the management of TMJ ankylosis, and two considered total joint replacement prostheses.

RCSEng[5] does not recommend surgical treatment for TMD patients with no functional limitation. For patients with arthrogenous TMD posing significant functional limitation, arthrocentesis is recommended as a first-line surgical measure. Little benefit for arthroscopy over arthrocentesis was found at the time of publication. The guidelines outline a number of surgical procedures for the management of recurrent TMJ dislocation, including autologous blood injection, eminectomy, eminoplasty, or down-fracture of the zygomatic arch. Finally, both RCSEng[5] and NICE[10] agree that total joint replacement should only be considered in cases of end-stage disease, for example rheumatoid arthritis, where more conservative options have failed. Guidance from RCDSO[11] supports these positions, adding that orthognathic surgery primarily for the management of TMD is not recommended.

Al-Moraissi et al.[62] conducted a moderate quality systematic review on the use of orthognathic surgery for the management of TMD. Twenty-nine studies on patients undergoing sagittal split osteotomy, intraoral vertical ramus osteotomy, Le Fort I osteotomy, or combinations of these were included. Overall, a statistically significant reduction in TMD after orthognathic surgery was found. However, a significant percentage of patients showed no improvement or worsening symptoms, with some previously asymptomatic patients developing post-surgical TMD. As a result, the authors concluded that there was insufficient evidence to suggest that surgery would predictably improve symptoms of TMD.

Based on this finding, this review supports the recommendation against the use of orthognathic surgery primarily for the management of TMD.

Minimally invasive surgery

Two moderate quality systematic reviews compared the efficacy of TMJ arthrocentesis and/or arthroscopy with non-surgical treatment for the management of arthrogenous TMD, including disc displacement without reduction. Meta-analyses from both reviews found statistically significant improvement in pain intensity with lavage compared to non-surgical treatment at 3 and 6 months. However, both reviews found no statistically significant difference in mouth opening between the groups at any review period up to 6 months. Both authors concluded that the current evidence did not show any advantage for TMJ lavage over non-surgical treatment; therefore, it is clear that conservative measures should be considered before invasive measures are employed[63,64].

A moderate quality systematic review by Al-Moraissi[65] compared the efficacy of arthrocentesis and arthroscopy for the management of anchored disc phenomenon, closed lock, anterior disc displacement with or without reduction, capsulitis, synovitis, and internal derangement. Meta-analyses showed statistically significant improvements in pain and maximum inter-incisal opening with arthroscopy compared to arthrocentesis. No significant difference in incidence of postoperative complications was found between the groups. The authors concluded that although the current evidence was limited, arthroscopic lysis and lavage appeared to have greater efficacy over arthrocentesis in the management of arthrogenic TMD.

Al-Moraissi[66] also conducted a moderate quality systematic review comparing the efficacy of arthroscopic lysis and lavage with arthroscopic surgery, including electrocautery of the pterygoid ligament, myotomy of the lateral pterygoid muscle, motor debridement, and disc suturing, for internal derangement. Patients with anchored disc phenomenon, disc displacement with reduction, painful click, and closed lock were included. Meta-analyses revealed significant improvements in pain and maximum inter-incisal opening with arthroscopic surgery compared to arthro-

scopic lysis and lavage. The sample sizes of these analyses were small, ranging from 113 to 250 participants.

In the same review, Al-Moraissi[66] compared the efficacy of arthroscopic surgery, including the procedures previously detailed, with open surgery, including discectomy, meniscoplasty, high condylectomy, disc repositioning, repair of perforation, and arthroplasty for the management of internal derangement. After meta-analysis, the authors concluded that open surgery was more effective at reducing pain at up to 5 years postoperative than arthroscopic surgery for patients with internal derangement. However, outcomes for maximum inter-incisal opening, jaw function, and other clinical findings were similar. It should be noted that sample sizes of these analyses were small, ranging from 66 to 104 participants.

The most recent systematic review by Al-Moraissi et al.[67] ranked the efficacy of all management options for arthrogenous TMD, both surgical and non-surgical. The authors found that there was very low to moderate quality evidence to suggest that intra-articular injection of corticosteroid and HA, arthrocentesis with HA or corticosteroid, and arthroscopy alone or with PRP or HA provided significant pain relief or improvement in maximum mouth opening compared to placebo in the short and intermediate term. The very low to moderate quality evidence available did not suggest that conservative treatment or physical therapy provided effective symptomatic relief of arthrogenous TMD. Therefore, contrary to previous findings by Bouchard et al.[63] and Fakhry and Abd-Elwahab Radi[64], the authors concluded that new evidence indicated that minimally invasive procedures, particularly in combination with pharmacological adjuvants, were significantly more effective at managing arthrogenous TMD than conservative treatments. Minimally invasive procedures should therefore be considered as a first-line treatment, or considered early in the management process if patients do not show clear improvement with conservative treatment.

In a moderate quality systematic review, Nagori et al.[68] compared the outcomes of single puncture arthrocentesis with standard double-needle arthrocentesis for patients with anchored disc phenomenon, closed lock, anterior disc displacement with or without reduction, capsulitis, synovitis, and internal derangement. The qualitative synthesis of five RCTs showed comparable reduction in pain and improvement in maximum mouth opening between the two techniques, with no significant difference in ease of operation or operating time.

Based on the above findings, this review recommends the early consideration of arthrocentesis or arthroscopy for cases of arthrogenous TMD, particularly internal derangement, when initial conservative therapy has provided no benefit. The use of pharmacological adjuvants should be considered on a case-by-case basis.

Platelet-rich plasma injection

None of the included guidelines made reference to the use of PRP injection for the management of TMD.

Three moderate quality systematic reviews investigated the efficacy of PRP injection alone or in combination with arthrocentesis or arthroscopy for the management of TMJ osteoarthritis. Meta-analyses by Chung et al.[69] and Haigler et al.[70] found a significant improvement in pain reduction with PRP injection compared to HA or saline injection or no injection. Both authors found no significant difference in the improvement of maximum mouth opening between the groups. The qualitative synthesis by Bousnaki et al.[71] appears to support these findings.

Overall, only Chung et al.[69] conclusively determined that PRP injection was an effective adjuvant to arthrocentesis or arthroscopy for pain reduction in TMJ osteoarthritis. Haigler et al.[70] and Bousnaki et al.[71] agreed that although favourable results were obtained with PRP injection, further high quality trials were needed before definitive conclusions could be made.

In summary, based on the above evidence this review indicates the need for further high quality research on the efficacy of PRP injection for the management of TMJ osteoarthritis before any recommendations can be made.

Management of TMJ ankylosis

Four moderate quality systematic reviews on the management of TMJ ankylosis were identified. Reviews compared the postoperative outcomes of various surgical techniques including gap arthroplasty, interpositional gap arthroplasty, reconstruction arthroplasty, distraction osteogenesis (DO), and alloplastic or autogenous joint reconstruction. Most studies evaluated were retrospective cohort studies or non-randomized clinical trials[72–75].

Three reviews considered the efficacy of gap arthroplasty, interpositional gap arthroplasty, and reconstruction arthroplasty in improving maximum incisal opening and reducing the re-ankylosis rate. Whilst all reviews showed benefits with all three surgical options for these outcomes[73], Al-Moraissi et al.[72] and Mittal et al.[75] found a significantly improved maximum incisal opening and recurrence rate with interpositional gap arthroplasty compared to gap arthroplasty. When comparing interpositional gap arthroplasty with reconstruction arthroplasty, two reviews found no significant difference in these outcomes between the two groups[74,75]. Overall, De Roo et al.[73] found that all three surgical techniques were comparably beneficial for improving maximum mouth opening, although reconstruction arthroplasty produced the best result. Mittal et al.[75] compared the postoperative outcomes from the use of autogenous or alloplastic reconstruction materials. Whilst no significant difference in maximum incisal opening or recurrence rate was found in reconstruction arthroplasty, interpositional gap arthroplasty with autogenous material resulted in a significantly lower recurrence rate compared with interpositional gap arthroplasty with alloplastic material.

Only Mittal et al.[75] examined the efficacy of DO, finding significantly improved maximum mouth opening with DO compared to interpositional gap arthroplasty or reconstruction arthroplasty. However, no significant difference in the re-ankylosis rate was found.

Al-Moraissi et al.[72] compared the efficacy of TMJ reconstruction with alloplastic or autogenous material. Analyses of three studies showed a significant improvement in maximum inter-incisal opening with the autogenous reconstruction compared to alloplastic reconstruction, however the opposite was seen with regards to postoperative pain.

Overall, all reviews found the available evidence was limited in quality and quantity. De Roo et al.[73] found that gap arthroplasty, interpositional gap arthroplasty, and reconstruction arthroplasty produced comparable improvements in maximum mouth opening. Two reviews concluded that gap arthroplasty resulted in poorer outcomes compared to interpositional gap arthroplasty or reconstruction arthroplasty[72,75], with two reviews agreeing that interpositional gap arthroplasty and reconstruction arthroplasty produced comparable outcomes[74,75].

In summary, based on the above evidence, this review supports the use of gap arthroplasty, interpositional gap arthroplasty, or reconstruction arthroplasty for the management of TMJ ankylosis. The

choice of procedure should be made on a case-by-case basis; however, particular consideration in favour of interpositional gap arthroplasty or reconstruction arthroplasty over gap arthroplasty should be made.

Management of TMJ luxation

Three moderate quality systematic reviews evaluated the efficacy of various management options for TMJ luxation. These included open surgeries such as eminectomy, eminoplasty, down-fracture of the zygomatic arch, glenotemporal osteotomy of the zygomatic arch, electrothermal capsulorrhaphy, and disc plication, as well as the injection of autologous blood, OK-432, or modified dextrose into the joint space[76–78].

Based on the qualitative synthesis of eight RCTs, Abrahamsson et al.[76] concluded that from the highly limited available evidence, autologous blood injection into the superior joint space and pericapsular tissues, in combination with intermaxillary fixation, received the strongest support for reducing the recurrence of TMJ luxation and improving inter-incisal opening. A systematic review by Tocaciu et al.[78] supported these findings. The authors concluded that the evidence supported the trial of injection of autologous blood or modified dextrose to reduce the recurrence of TMJ luxation.

Evidence from RCTs on surgical procedures for TMJ luxation is lacking. The qualitative analysis of cohort studies, case series, and case reports undertaken by Tocaciu et al.[78] and de Almeida et al.[77] found no clear advantage for any surgical procedure. Tocaciu et al.[78] concluded that disc plication, eminectomy, and eminoplasty resulted in comparably high success rates, therefore treatment decisions should be made on a case-by-case basis. de Almeida et al.[77] noted that eminectomy was often used as a 'rescue procedure' in cases of post-surgical relapse, which may indicate that surgeons empirically consider this to be the optimal treatment for TMJ luxation.

These findings support the consideration of autologous blood injection into the joint space for the management of TMJ luxation, although further evidence is required. Surgical methods of managing TMJ luxation should be determined on a case-by-case basis.

TMJ replacement prostheses

Guidelines from NICE[9] on total prosthetic replacement of the TMJ outline that a number of different prostheses are available for this procedure.

Two moderate quality systematic reviews compared the outcomes produced by the custom-made TMJ Concepts, stock and custom-made Biomet, and stock and custom-made Nexus total joint replacement systems. Both reviews concluded that all systems produced comparable reductions in pain and increases in maximum inter-incisal opening[79,80]. Zou et al.[80] found no significant difference in these outcomes between stock and custom-made prostheses of any system. Both reviews compared diet score data for the TMJ Concepts and Biomet systems only, finding that the improvements in the two systems were similar[80].

In summary, the findings of the present review recommend that the choice of prosthetic system used for TMJ replacement continues to be made on a case-by-case basis.

All treatment modalities

Song et al.[81] conducted a critically low quality review to investigate the effect of any treatment modality on the oral health-related quality of life of TMD patients. The qualitative synthesis of one RCT and four cohort studies revealed some beneficial effects with orthodontic treatment with or without orthognathic surgery, occlusal splint therapy, arthrocentesis, amitriptyline, and CBT. However, due the limited number of identified studies evaluating oral health-related quality of life, the authors were unable to reach definitive conclusions.

Discussion

Great variation exists in the methodology of rapid reviews[82]. This review used the methodology outlined by Khangura et al.[7]. Like traditional systematic reviews, this method maintained a rigorous systematic approach towards the literature search, article selection, and quality assessment performed independently by two reviewers. However, unlike traditional systematic reviews, rapid reviews can address broad research questions with broad inclusion criteria in terms of population, interventions, comparisons, outcomes, and study designs[7]. Rather than focus on a quantitative synthesis, the narrative synthesis of results aims to provide a summary, as well as a sense of volume and direction, of the available evidence[7,82]. This approach is better suited for providing a summary of recent evidence on all treatment modalities for all types of TMD.

In summary, the evidence from systematic reviews published in the past 5 years is supportive of a staged multi-modal conservative approach towards the initial management of TMD. First, simple self-management techniques, alongside simple analgesics and appropriate physiotherapy, are non-invasive techniques that have been shown to provide some benefit. Second, emerging evidence on alternative therapies shows that they may provide some symptomatic relief; however, further high quality research is required. Third, there is a lack of evidence to support the efficacy of occlusal splint therapy, occlusal adjustment, or prosthodontic therapy, therefore these approaches should not be routinely recommended. Fourth, further high quality evidence is required to better understand the efficacy of oral pharmacotherapeutics for chronic TMD. Intramuscular or intra-articular pharmacotherapeutics should only be considered if conservative methods fail. The evidence reviewed supports the use of intramuscular botulinum toxin in cases of myospasm or muscle hyperactivity-related myalgia, as well as intra-articular HA for the management of arthrogenic TMD including TMJ osteoarthritis, rheumatoid arthritis, and internal derangement. Corticosteroid injection for arthrogenic TMD should be considered with caution on a case-by-case basis. Fifth, the use of arthrocentesis or arthroscopy has shown benefits in cases of arthrogenous TMD where conservative measures fail, and should be considered as a first-line surgical measure for internal derangement. Further high quality research on the efficacy of PRP injection for the management of TMJ osteoarthritis is needed before any recommendations can be made. Sixth, open joint surgery has shown benefit for cases of severe arthrogenous disease. Surgical methods for managing TMJ luxation and TMJ ankylosis should be determined on a case-by-case basis. Finally, the vast majority of systematic reviews included were of moderate quality, indicating that they provided an accurate summary of the studies included. The consensus of recently published guidance on the management of TMD supports these findings, with all guidelines favouring a multi-modal conservative approach towards initial management. More complex pharmaceutical management should be reserved for cases of chronic TMD that cannot be managed with simpler initial therapy, whilst surgical therapy should be used only for severe arthrogenous disease.

This rapid review collates 62 systematic reviews on a large variety of different

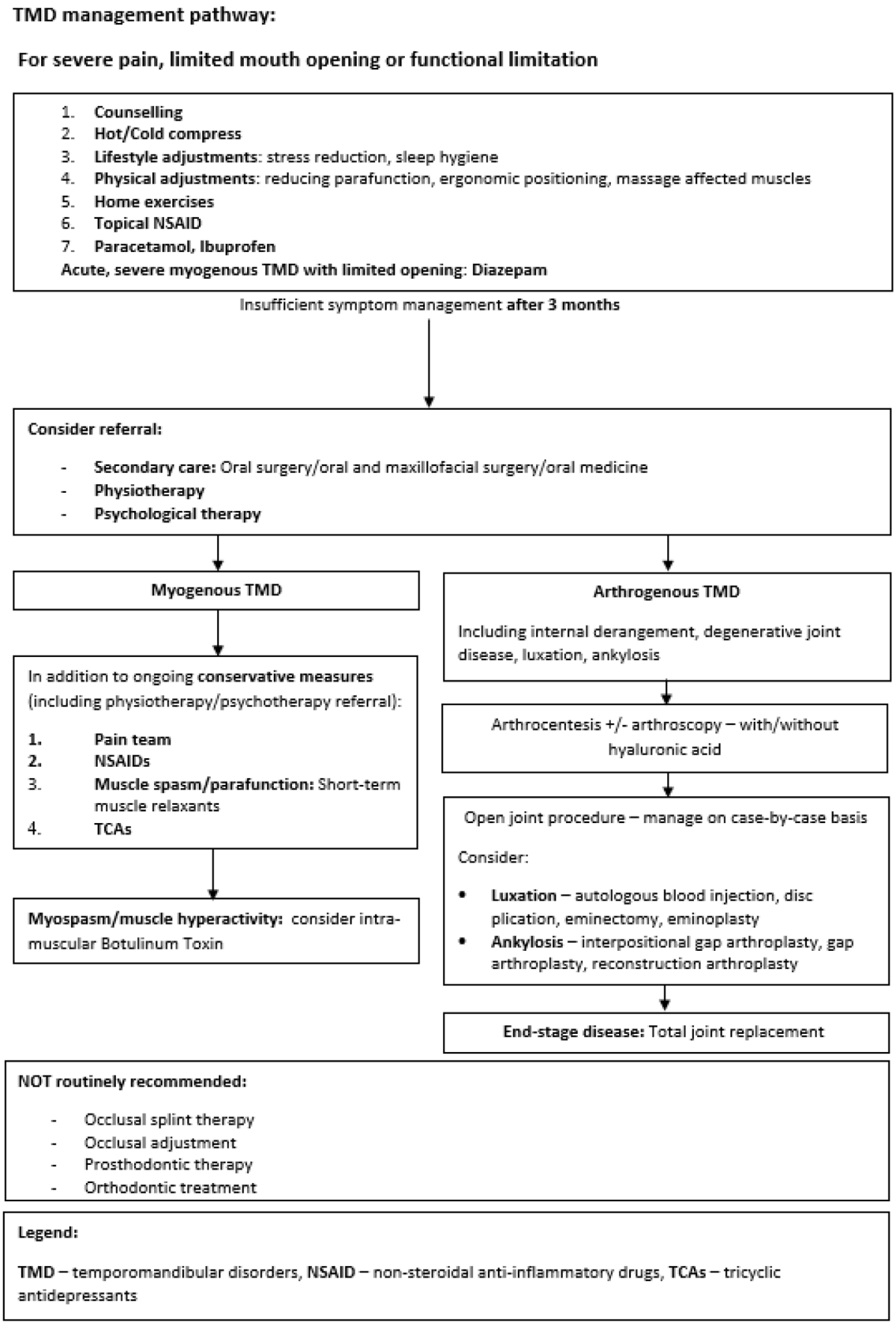

Fig. 2. Management pathway for temporomandibular disorders.

treatment modalities for TMD, making it the largest review of its nature at the time of publication. The most recent review of systematic reviews was published in 2010 by List and Axelsson[83], who included 38 systematic reviews on a variety of treatment modalities for TMD. The analysis of systematic reviews, rather than the primary literature, allows conclusions to be made based on the largest and most reliable body of available evidence. This also allows practitioners and guideline developers to gain a comprehensive view of the consensus and quality of recent evidence.

The strengths of this review include its use of a comprehensive search strategy across five databases and rigorous study selection, data extraction, and quality assessment undertaken by two independent reviewers. The research team consisted of members from oral medicine, oral and maxillofacial surgery, and dental public health, providing a strong multidisciplinary approach to the synthesis of the findings.

The pragmatic methodology of a rapid review introduced some limitations[7].The exclusion of articles not in the English language or unavailable through King's College London may have introduced some bias to the review findings; however the documents included covered a substantial breadth of relevant topics. Restriction to a 5-year review period may have excluded landmark systematic reviews published since the last national guidelines were released in 2013[5]; however, this was considered reasonable because of the desire to include more recent research that may not have been included in guidelines. Moreover, an assessment of the percentage of primary studies cited in more than one included systematic review was not performed, which would have provided additional insight into the level of overlap between similar reviews.

The findings of this review are summarized in a management pathway developed for both primary and secondary care (see Fig. 2). The aim of the proposed pathway is to ensure consistent and evidence-based management of TMD across all disciplines and encourage wider debate. Given the relatively high prevalence of this condition[1], as well as the transient nature of symptoms in acute cases, an emphasis has been placed on the use of effective, non-invasive initial management in primary care. It is hoped that this will reduce the volume of TMD referrals to secondary care, allowing resources to be directed towards the treatment of severe, chronic TMD using more complex or invasive techniques.

In terms of future research, further evidence is needed to better inform management strategies for chronic TMD, particularly in the areas of pharmacotherapy and surgical therapy. As the aetiology of TMD is often a combination of various biopsychosocial factors, further insight is needed into how these play a role in determining management decisions and treatment success. The majority of studies reviewed primarily assessed pain or maximum mouth opening to determine treatment outcomes. However, due to the biopsychosocial nature of TMD, the impact of treatment can be more holistically assessed using patient-reported outcome measures. Future research should include further assessment of outcomes such as quality of life and functional limitation.

In conclusion, there is moderate evidence to support a multi-modal conservative approach towards the initial management of TMD. Non-invasive techniques such as self-management, simple analgesics, and physical therapy have shown some benefit. Further research is required to investigate emerging evidence that alternative therapies provide some symptomatic relief. There is a lack of evidence to support the efficacy of occlusal splint therapy, occlusal adjustment, or prosthodontic therapy. The evidence surrounding oral pharmacotherapeutics for chronic TMD is low and requires further development. However, there is low to moderate quality evidence that intra-articular corticosteroid or hyaluronic acid for arthrogenic TMD, or intra-muscular botulinum toxin for myogenic TMD may be beneficial for selected cases of chronic disease if conservative measures fail. Moderate quality evidence shows that the use of arthrocentesis or arthroscopy has shown benefits in cases of arthrogenous TMD where conservative measures fail, whilst moderate quality evidence supports the use of open joint surgery for severe arthrogenous disease. Consideration of the aetiological factors of the disorder must be made when determining management strategies for chronic TMD.

Funding

None.

Competing interests

None.

Ethical approval

Not applicable.

Patient consent

Not applicable.

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.ijom.2021.11.009.

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