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The effectiveness of self-management interventions in adults with chronic orofacial pain: A Systematic review, Meta-analysis and Meta-regression

[1]Aggarwal VR, [2] Fu Y, [3]Main CJ, [1]WU J

[1] School of Dentistry, Faculty of Medicine & Health, University of Leeds.

[2] School of Healthcare, Faculty of Medicine & Health, University of Leeds.

[3] Research Institute for Primary Care & Health, Keele University

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Correspondence

Dr Vishal R. Aggarwal

Clinical Associate Professor in Acute Dental Care and Chronic Pain,

School of Dentistry, Faculty of Medicine & Health, University of Leeds,

Worsley Building, Clarendon Way, Leeds LS2 9LU

E-mail: v.r.k.aggarwal@leeds.ac.uk

Tel: 0113 343 6122

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Significance: This systematic review provides clear evidence for effectiveness of combined biomedical and psychological interventions (incorporating self-management approaches) on long term outcomes in the management of chronic orofacial (principally TMD) pain. Self-management should be a priority for early intervention in primary care in preference to invasive, irreversible and costly therapies. Further research is needed firstly to clarify the relative effectiveness of specific components of self-management, both individually and in conjunction, and secondly on outcomes in other types of chronic orofacial pains.

ABSTRACT

Background

Psychosocial risk factors associated with chronic orofacial pain are amenable to self-management. However, current management involves invasive therapies which lack an evidence base and have the potential to cause iatrogenic harm.

Objectives:

To determine: 1) whether self-management is more effective than usual care in improving pain intensity and psychosocial well-being 2) optimal components of self-management interventions.

Databases and Data treatment

Cochrane Oral Health Group Trials Register, Cochrane Central Register of Controlled Trials, MEDLINE, EMBASE, PsycINFO, WHO International Clinical Trials Registry Platform and Clinical Trials.gov were searched. Meta-analysis was used to determine effectiveness and GRADE was used to rate quality, certainty and applicability of evidence.

Results

Fourteen trials were included. Meta-analyses showed self-management was effective for long-term pain intensity (standardised mean difference (SMD) -0.32, 95% confidence interval (CI) -0.47 to -0.17) and depression (SMD -0.32, 95% CI -0.50 to -0.15). GRADE analysis showed a high score for certainty of evidence for these outcomes and significant effects for additional outcomes of activity interference (-0.29 95% CI -0.47 to - 0.11) and muscle palpation pain (SMD -0.58 95% CI -0.92 to -0.24).

Meta-regression showed non-significant effects for biofeedback on long-term pain (-0.16, 95% CI -0.48 to 0.17, P-value = 0.360) and depression (-0.13, 95% CI -0.50 to 0.23, P-value = 0.475).

Conclusions

Self-management interventions are effective for patients with chronic orofacial pain. Packages of physical and psychosocial self-regulation and education appear beneficial. Early self-management of chronic orofacial pain should be a priority for future testing.

BACKGROUND

Persistent pain in the face or mouth is a frequent causes for consultation in both primary dental and medical care and in a substantial proportion of cases it can become both chronic and disabling (Aggarwal et al., 2008; Macfarlane et al., 2002). Subjects who report orofacial pain for three months or more report increased pain level and disability and are also more likely to seek treatment and take medication (Macfarlane et al., 2002). Chronic orofacial pain (OFP) is the characteristic feature of a number of clinical conditions such as temporomandibular joint disorder (TMD), burning mouth syndrome, atypical odontalgia and atypical facial pain that are difficult to diagnose and treat (Durham et al., 2007; Elrasheed et al., 2004; Pfaffenrath et al., 1993). TMD is globally the most common orofacial pain condition and in the United States a prevalence of 6% in women and 3.5% in men has been reported (Lipton et al., 1993); in the UK the prevalence of chronic orofacial pain is similar at 7% (Aggarwal et al., 2006). The American Academy of Orofacial pain suggests that in any given year 10% of women and 6% of men (approximately 20 million adults) have TMD pain (Gatchel et al., 2006). Reports from European studies also have similar prevalence figures (6.7%) for TMD (Johansson et al., 2003).

Patients with chronic orofacial pain are likely to be frequent consulters to primary, secondary and tertiary care and undergo multiple investigations to determine an organic cause for their symptoms - although underlying organic pathology is rarely found (Durham et al., 2007; Elrasheed et al., 2004; Pfaffenrath et al., 1993). Management of chronic orofacial pain by dentists tends to focus on correction of local mechanical factors such as teeth grinding and malocclusion. However evidence in the form of Cochrane systematic reviews has shown little or no beneficial effects of invasive physical therapies such as irreversible occlusal adjustments (Koh and Robinson 2003) and oral splints (Al-Ani et al., 2005; List and Axelsson 2010). Indeed an audit of 101 consecutive referrals of persistent orofacial pain to a secondary care Oral Surgery department (Beecroft et al., 2013) showed that patients had been treated in nine different hospitals; referred to 15 distinct specialties with a mean of 7 consultations per specialty. Overall 341 treatment attempts had been made and only 24% yielded a successful outcome. The study concluded that there was a need for evidence based management and specialist regional centres (Beecroft et al., 2013).

Patients with orofacial symptoms also frequently consult their general medical practitioner (69%) rather than general dental practitioners (31%) (Bell et al., 2008). General medical practitioners do not have the infrastructure or knowledge to manage chronic orofacial pain and indeed find it difficult (Peters et al., 2015). Patients are therefore referred from specialist to specialist and have multiple tests, investigations and often invasive and irreversible treatments that do not improve symptoms (Beecroft et al., 2013; Durham et al., 2007; Elrasheed et al., 2004; Pfaffenrath et al., 1993). Costs of TMD alone in the United States are in the region of $4 billion annually (Gatchel et al., 2006) and a study examining the costs to the UK National Health Service (Durham et al., 2016b) showed that consultation costs were a significant proportion ($p<0.001$) of cumulative healthcare utilization costs of patients with persistent orofacial pain. This imposes a huge burden on already stretched health care resources. The descriptive epidemiology of chronic orofacial shows a strong association with psychosocial risk factors (Aggarwal et al., 2008; Bair et al., 2016; Slade et al., 2007; Slade et al., 2016) and a co-occurrence with other long term conditions like chronic widespread pain (CWP), irritable bowel syndrome (IBS) and chronic fatigue (CF) (Aggarwal et al., 2006; Bair et al., 2016; Slade et al., 2016).

In line with a global drive to curb the epidemic of non-communicable diseases and long term conditions, UK government policy places an emphasis on using self-management to improve management of long term conditions through patient participation and ownership of their own healthcare (Department of Health 2001; 2005). Self-management approaches (where the person takes an active role in managing their condition rather than a passive one that is more dependent on others) are increasingly accepted for chronic pain (Nicholas and Blyth 2016). This term refers to all actions taken by individuals to manage the symptoms, treatment, physical and psychosocial consequences and lifestyle changes inherent in living with a chronic condition (Barlow et al., 2002). Self-management interventions aim to increase the capacity, confidence and efficacy of the individual and are increasingly viewed as core strategies of the management of chronic conditions (Kennedy et al., 2013). Education and skill development are two common components of those interventions that are tailored to influence individual's cognitive, behavioural and emotional responses to maintain and strengthen a satisfactory quality of life (Barlow 2001). The boundary between "active" and "passive" treatment however is not absolute and it could be argued that anything done by the patient in an endeavour to better manage their symptoms, function or associated distress could be viewed as self-management. However the term self-management approach, normally has a specific cognitive or behavioural focus and is normally contrasted with passive treatment primarily delivered by a healthcare practitioner. Currently it is normally taken to apply to pain coping strategies employed by the patient to help manage their pain and its impact. This aligns with TMD interventions which aim to target these factors using techniques such as psychoeducation, relaxation, jaw posture control, cognitive behaviour therapy (CBT) and biofeedback as per previous studies (Goldthorpe et al., 2016a; Litt et al., 2009; Turner et al., 2007; Turner et al., 1995). These studies have not only outlined components for biopsychosocial interventions for chronic orofacial pain and TMD but also explored the mechanisms by which self-care interventions involving both psychosocial self-care and jaw posture control can bring about change in patients with chronic orofacial pain. Guided self-care interventions can target vicious cycles associated with both fear-avoidance behaviour (central pain processing mechanisms) and 'anxiety-pain-tension' cycles involving muscle over activity linked to emotional stress (depression, anger, fears and anxieties about the pain) which in turn may increase pain by precipitating activity in psychophysiological systems. By changing patient beliefs and developing coping strategies self-management interventions have the potential to induce a return to normal functioning. (Goldthorpe et al., 2016a; Litt et al., 2009; Turner et al., 2007; Turner et al., 1995). Such interventions are non-invasive and have the potential, if effective, to be applied across healthcare and delivered by general medical practitioners to whom patients with orofacial symptoms frequently consult.

Key components of such interventions have included psychoeducation, relaxation, CBT and biofeedback (Goldthorpe et al., 2016a; Litt et al., 2009; Turner et al., 2007; Turner et al., 1995). However biofeedback, in particular EMG biofeedback (Gatchel et al., 2006), requires not only expensive equipment but also time spent on training and particularly time spent by patients on practice. This may not be amenable to self-management particularly for interventions that need to be delivered remotely by telephone or web-based interactions.

The aim of the current review was therefore to assess the effectiveness of self-management interventions compared with usual care in the management of adults with chronic orofacial pain.

Specific Objectives:

1. To determine whether, in adults with chronic orofacial pain including temporomandibular disorders (TMD), self-management interventions more effective than usual care in improving long term outcomes related to pain intensity and psychosocial well-being.
2. To determine whether the biofeedback component of interventions shows an additional treatment effect compared to no biofeedback.
3. To determine the effectiveness of self-management for subtypes of chronic orofacial pain in particular TMD which is the most common subtype.

METHODS

This systematic review and meta-analysis was undertaken following the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) statement (Liberati et al., 2009; Moher et al., 2009). This study is registered with PROSPERO (CRD42017060158 (Aggarwal et al., 2018)).

Criteria for considering studies for this review

Types of studies

Randomised controlled trials which included self-management of chronic orofacial pain compared with any other form of treatment such as surgery, usual care, pharmacological treatment and/or waiting list controls.

Types of participants

Adults over 18 years of age with chronic orofacial pain defined as those diagnosed with the following conditions: temporomandibular disorders (TMD), atypical facial pain, atypical odontalgia and burning mouth syndrome. Other terms used to describe these conditions were also included in the search strategy e.g. myofacial pain, myofascial pain related to the facial region, craniomandibular/oromandibular dysfunction, mandibular stress syndrome, facial arthromyalgia, masticatory muscle disorder, masticatory myalgia, TMJ syndrome, stomatodynia, persistent idiopathic facial pain, persistent dento-alveolar pain.

Types of outcome measures

Primary outcomes

1. Pain intensity (short and/or long term) measured using a visual analogue scale or a validated categorical scale e.g. Brief Pain Inventory, Multidimensional Pain Inventory.
2. Depression / Anxiety (long and short term using validated scales for example Hospital Anxiety and Depression Scale.
3. Interference with life – pain impact on activities of daily living measured using e.g. Brief Pain Inventory, Multidimensional Pain Inventory.

Types of interventions

Self-management interventions were defined as those that included patient participation in the intervention. Table 1 illustrates the components of the interventions. Trials were eligible for inclusion into self-management as they included patient participation through a patient manual and/ or between session work as part of the intervention protocol. Other components were education, psychological such as Cognitive Behaviour Therapy or its components (Cognitive therapy, behavioural therapy) and physical self-regulation for example posture control, habit reversal, relaxation and/or biofeedback. Table 1 summarises the intervention components of studies and how these map onto self-management.

Search methods for identification of studies

For the identification of studies included or considered for this review, detailed search strategies were developed for each database searched. These were based on the search strategy developed for MEDLINE (OVID) but revised appropriately for each database.

The search attempted to identify all relevant studies irrespective of language. Electronic searches

The following electronic databases were searched (to 29 September 2017): The Cochrane Oral Health Group Trials Register, the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE via OVID, EMBASE via OVID, PsycINFO via OVID, WHO International Clinical Trials Registry Platform and Clinical Trials.gov. There were no restrictions regarding language or date of publication. The search strategy used a combination of controlled vocabulary and free text terms for identifying randomised trials (RCTs) in MEDLINE. Details of the search strategy are provided in Appendix 1.

Searching other resources

The reference lists of all eligible trials were checked for additional studies. Where these had not already been searched the journals were hand searched by the review authors if electronic copies were not available.

Data collection and analysis

Selection of studies

The title and abstracts of relevant articles and reports from the search strategy outlined in Appendix 1 were screened independently by two review authors (VA and JW). Full reports were obtained where trials met the inclusion criteria or where a clear decision could not be made from the title or abstract. Disagreements were resolved by discussion and full reports of all studies potentially meeting the inclusion criteria were obtained. Full reports were used to assess trials where inclusion was unclear and reasons for rejection were clear upon examining full reports. Main reasons for rejection were: studies were not randomised controlled trials, had the wrong disease definition and / or patient group.

Data extraction and management

Data was extracted, independently and in duplicate, using a previously prepared data extraction form which included the characteristics of trial participants, interventions, control groups and outcomes. Characteristics of included studies are presented in appendix 2. VA extracted all the studies while JW and YF shared equally extraction for the purpose of duplication. Any differences were resolved by discussion. Differences involving risk of bias were resolved by using the most frequent option selected e.g. if two of the three reviewers were in agreement then we chose that option. There were no instances where there was disagreement between all 3 reviewers. Prior to extraction the data extraction form was piloted using three studies and all authors extracting the data participated in the piloting so that they were clear about the extraction process. The data extraction form was modified for ease of use following the pilot extractions.

Assessment of risk of bias in included studies

The assessment of risk of bias in the included trials was undertaken independently and in duplicate as part of the data extraction process by three of the review authors (VA, JW and YF) as described above and in accordance with the Cochrane Handbook for Systematic Reviews of Interventions 5.0.2 (Higgins and Green 2011). Included trials were assessed on the following criteria:

- adequate sequence generation
- concealed allocation of treatment
- blinding of participants/caregivers (where feasible) and outcome assessors
- incomplete outcome data
- selective outcome reporting
- any other bias relevant to the study

A description of the quality items was tabulated for each included trial, along with a judgement of low, high or uncertain risk of bias. Criteria for risk of bias judgements regarding allocation concealment were as described in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins and Green 2011):

- Low risk of bias - adequate concealment of the allocation (e.g. sequentially numbered, sealed, opaque envelopes or centralised or pharmacy-controlled randomisation).
- Uncertain risk of bias - uncertainty about whether the allocation was adequately concealed (e.g. where the method of concealment is not described or not described in sufficient detail to allow a definite judgement).
- High risk of bias - inadequate allocation concealment (e.g. open random number lists or quasi-randomisation such as alternate days, date of birth, or case record number).

A summary assessment of the risk of bias for the primary outcome (across domains) within and across studies was undertaken. Within a study, a summary assessment of low risk of bias was given when there was a low risk of bias for all key domains, unclear risk of bias when there was an unclear risk of bias for one or more key domains, and high risk of bias when there was a high risk of bias for one or more key domains. Across studies, a summary assessment was rated as low risk of bias when most information is from studies at low risk of bias, unclear risk of bias when most information was from studies at low or unclear risk of bias, and high risk of bias when the proportion of information was from studies at high risk of bias sufficient to affect the interpretation of the results.

Measures of treatment effect

For dichotomous outcomes, treatment effects were expressed as risk ratios with 95% confidence intervals whilst for continuous outcomes mean differences with 95% confidence intervals were used. All analyses were performed using R version 3.4.1 (https://cran.r-project.org/)(R Core Team 2013).

Assessment of heterogeneity

Clinical heterogeneity was accounted for by inclusion criteria for uniform disease definition, assessing components of the interventions and outcome measures included in the trials. Statistical heterogeneity was assessed by means of Cochrane *Q*, where a large *Q* value indicates the presence of heterogeneity, and the I^2 statistic where I^2 gives the percentage of variability in the effect estimate that is due to heterogeneity rather than to chance. Suggested thresholds for the interpretation of I^2 are as follows: less than 40% indicate there is no problem with heterogeneity, 30–60% indicates a moderate problem, 60–90% a substantial problem and 75% and over considerable heterogeneity (Higgins and Green 2011).

Assessment of reporting biases

Reporting biases were assessed through funnel plots for outcomes that were reported by more than 5 studies. Egger's test was used to test the statistical significance of reporting biases for each outcome.

Data synthesis

Meta-analyses were only carried out if trials were of similar comparisons reporting the same outcome measures. Estimates of effect were combined using a random-effects model. Mean differences or standardised mean differences were used for the same outcomes with different scales.

Quality of evidence

We used the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach to assess the quality and certainty of the body of evidence per outcome, in accordance with the Cochrane Handbook for Systematic Reviews of Interventions 5.0.2 (Higgins and Green 2011). For the most important outcomes, we used the programme GRADE pro GDT 2015 to generate a certainty of evidence table (Table 2). Starting from an assumed level of high quality, this reduced the quality of the evidence by one or more levels if there were one or more limitations in the risk of bias, consistency, and/or precision of the pooled estimate. The level of evidence as then rated as either high, moderate, low or very low depending on the number of limitations.

Assessment of intervention components:

Meta-regression

Simple mixed-effects meta-regression was used to investigate whether biofeedback provided additional treatment effect. We performed meta-regression on outcome measures of long-term pain and depression between patients with biofeedback and those without biofeedback.

RESULTS

Description of studies

A detailed description of the studies is in the characteristics of included and excluded studies presented in appendix 2.

Results of the search

The initial search strategy yielded 1104 references which were assessed blind and independently by VA and JW, and based on the abstracts and titles these were reduced to 48 relevant manuscripts (Figure 1). Main reasons for exclusion were that a large proportion of studies were not trials and others were not on chronic orofacial pain.

All the 48 manuscripts identified above were extracted by the lead author VA. Extraction was duplicated by sharing blind and independently between the other co-authors (JW, YF). Sixteen manuscripts were relevant for analysis and are presented in the characteristics of included studies table in appendix 1. A number of trials that were duplicates of the same study were merged. Reasons for exclusion at this stage were interventions not compatible with self-management, had the wrong disease definition and/or patient group and they were not randomised controlled trials. Of the 16 studies which met all eligibility criteria and hence included in this review, Dworkin's 2 studies (Dworkin et al., 2002a; Dworkin et al., 2002b) and Komiyama's study (Komiyama et al., 1999) displayed results graphically and we did not have means and standard deviations to pool these studies. Authors were contacted to obtain data but only provided means and no standard deviations or did not respond. This left 14 studies for inclusion in the final meta-analysis (Figure 1).

Included studies

All of the included trials had comparable control groups comprising usual treatment which involved conservative treatment composed of education, counselling and an intra-oral flat plane appliance. The Bergdahl study (Bergdahl et al., 1995) included a control group of attention placebo and the Townsend study (Townsend et al., 2001) including a waiting list control with no intervention and were therefore not pooled in the meta-analysis as they had a different comparators. They were however used for the GRADE analysis (table 2).

The interventions for self-management were as defined previously. Outcome measures included short-term (3 months or less) and long term (more than 3 months) pain intensity and long term measures for muscle palpation pain, activity interference and depression.

Risk of bias in included studies

Risk of bias plots are displayed in Figure 2a and 2b; the former showing the overall risk of bias and the latter individual plots for each study. Figure 2c shows funnel plots for publication bias.

Blinding (performance bias and detection bias)

It is notable that due to the nature of the intervention, blinding was difficult where the intervention and controls were concerned. However it was possible for outcome assessment and for the purposes of this review we evaluated whether included studies had blinded outcome measurement. This was reported by seven of the included studies (Carlson et al., 2001; Dworkin et al., 1994; Ferrando et al., 2012; Gardea et al., 2001; Goldthorpe et al., 2017; Shedden-Mora et al., 2013; Turner et al., 2006) and three did not report at all (Bergdahl et al., 1995; Gatchel et al., 2006; Litt et al., 2010). The remaining studies were unclear (Figure 2b). The overall risk of bias was deemed low in this area (Figure 2a).

Incomplete outcome data (attrition bias)

Only three trials did not report on incomplete outcome data; nine fully reported this (Bergdahl et al., 1995; Carlson et al., 2001; Dworkin et al., 1994; Ferrando et al., 2012; Gardea et al., 2001; Gatchel et al., 2006; Goldthorpe et al., 2017; Shedden-Mora et al., 2013; Turner et al., 2006) and the one was unclear (Litt et al., 2010) and risk of bias (Figure 2b) was therefore low for this domain (Figure 2a).

Allocation (selection bias)

This was not reported by only three of the included studies (Ferrando et al., 2012; Litt et al., 2010); fully reported by four studies (Gardea et al., 2001; Goldthorpe et al., 2017; Shedden-Mora et al., 2013; Turner et al., 2006) and the remaining studies were unclear (Figure 2b). Overall the risk of bias in this area was therefore low (Figure 2a).

Selective reporting (reporting bias)

None of the included trials had selective reporting and therefore were assessed as being at low risk of bias for selective reporting (Figure 2a).

Publication Bias

There were only two outliers for short term pain intensity and one for long term pain intensity and activity interference for funnel plots (Figure 2c) which may indicate the existence of publication bias. However, formal tests showed that this was not statistically significant (Egger's test, P-value for short term pain = 0.35, long term pain = 0.52, activity interference = 0.34 and Long –term depression = 0.69).

Effectiveness of self- management interventions

Self- management interventions versus usual care Pain (short term)

Nine studies provided comparable data for this outcome (Carlson et al., 2001; Crockett et al., 1986; Dworkin et al., 1994; Ferrando et al., 2012; Gardea et al., 2001; Goldthorpe et al., 2017; Litt et al., 2010; Shedden-Mora et al., 2013; Turk et al., 1993).

Due to substantial heterogeneity (I^2 = 62%), the results of these studies could not be pooled (Figure 3). Hence no overall conclusions could be drawn for this domain. Of the studies that did not have quantitative data for this outcome, the Komiyama paper (Komiyama et al., 1999) showed no differences in pain intensity between the self-management intervention and control groups. In contrast the Dworkin comprehensive care programme study (Dworkin et al., 2002a) showed significant improvement in short-term pain intensities between self-management and usual care.

Self-management interventions versus usual care - Pain (long term)

Nine studies provided data on this outcome (Carlson et al., 2001; Dworkin et al., 1994; Gardea et al., 2001; Gatchel et al., 2006; Goldthorpe et al., 2017; Litt et al., 2010; Shedden-Mora et al., 2013; Turk et al., 1993; Turner et al., 2006).

Due to low heterogeneity (I^2 = 7%) the results of the studies could be pooled for the purpose of statistical analysis (Figure 4). This showed a statistically significant difference in favour of self-management interventions (SMD -0.32, 95% CI -0.47 to -0.17), and this represented a 16% improvement in long-term pain for self-care versus usual care for patients with chronic orofacial pain (Figure 4).

Considering subgroups of interventions, statistically significant differences were observed for self-care CBT (SMD -0.26, 95% CI -0.45 to -0.07) and combined biofeedback and CBT (SMD -0.46 95% CI −0.72 to −0.20) (Figure 4). Of the studies that did not have quantitative data for this outcome the Dworkin self-care intervention (Dworkin et al., 2002a) showed significant ($p<0.05$) improvement in long term pain intensity whist the comprehensive care programme study (Dworkin et al., 2002b) did not.

Self-management interventions versus usual care - Muscle palpation pain (long term)

Overall only three studies provided data on this outcome (Carlson et al., 2001; Turk et al., 1996; Turk et al., 1993).

Only three studies provided data on this outcome and because there was substantial heterogeneity (I=63%) the pooled results were unreliable although they showed a significant improvement in muscle palpation pain (SMD -0.58 95% CI −0.92 to −0.24) (Table 3). There was insufficient data to draw any conclusions regarding any of the individual interventions with regard to muscle palpation pain (long term). Of the studies that did not have quantitative data for this outcome the Dworkin self-care intervention (Dworkin et al., 2002a) showed significant ($p<0.05$) improvement in this outcome.

Self-management interventions versus usual care - Activity interference (long term)

A total of eight studies provided data for this outcome (Carlson et al., 2001; Dworkin et al., 1994; Ferrando et al., 2012; Gardea et al., 2001; Goldthorpe et al., 2017; Litt et al., 2010; Shedden-Mora et al., 2013; Turk et al., 1996).

Eight studies provided data for this outcome and there was a significant effect of the pooled results (SMD -0.29 95% CI -0.47, -0.11) (Table 3). However because there was substantial heterogeneity (I^2=79%) the pooled results are unreliable. Individually, there were statistically significant difference for self-care CBT (SMD -0.37 95% CI -0.57, -0.16). Of the studies that did not have quantitative data for this outcome the Dworkin self-care intervention (Dworkin et al., 2002a) showed significant

(p<0.05) improvement in this outcome whilst the comprehensive care programme study (Dworkin et al., 2002b) did not.

Self-management interventions versus usual care - Depression (long term)

A total of seven studies provided data for the statistical analysis for this outcome (Carlson et al., 2001; Gatchel et al., 2006; Goldthorpe et al., 2017; Litt et al., 2010; Shedden-Mora et al., 2013; Turk et al., 1996; Turk et al., 1993).

Overall seven studies provided data on this outcome and there were statistically significant differences in favour of psychosocial interventions (SMD -0.32, 95% CI -0.50 to -0.15) (Figure 5) and this represented a 25% improvement in long term pain for psychosocial interventions versus usual care. There was no heterogeneity (I^2=0%) (Figure 5).

Individually, both self-care CBT and CBT/biofeedback show statistically significant benefit over usual care with regard to depression (SMD -0.27, 95% CI -0.49 to -0.05) and (SMD -0.41, 95% CI -0.68 to -0.13) respectively (Figure 5).

Certainty of the evidence

The certainty of the evidence was high for the main outcome measures as assessed using GRADE criteria (Table 2). For the key outcome measures of long term pain intensity and depression there were 757 participants (12 RCTs) and 524 participants (8 RCTs) respectively.

For other outcome measures that were not pooled, the quality of evidence was also high and significant effects were observed for the effects of self-management interventions on activity interference (SMD -0.29, 95% CI -0.47 to -0.11) and long term muscle palpation pain (SMD -0.58, 95% CI -0.92 to -0.24). The effect for short term pain remained non-significant (SMD -0.06, 95% CI -0.21 to 0.09).

Subgroup analysis

A subgroup analysis for trials that only included TMD studies showed similar significant effects on long term pain and depression SMD -0.34 (-0.50, -0.19) and -0.33 (-0.51, -0.15) and results could be pooled due to low heterogeneity (Table 4).

Components of self-management

Meta regression was conducted to test whether biofeedback component showed an additional treatment effect compared with no biofeedback. The outcomes of long-term pain and depression were used to assess this effect. Of the 11 studies reporting long-term pain, 5 studies also used biofeedback in the intervention. The coefficient estimate from meta-regression for using

biofeedback was (-0.16, 95% CI -0.48 to 0.17, P-value = 0.360). Of the 8 studies reporting long-term depression, 3 studies also used biofeedback in the intervention. The coefficient estimate from meta-regression for using biofeedback was (-0.13, 95% CI -0.50 to 0.23, P-value = 0.475).

DISCUSSION

Summary of main results

This systematic review has shown for the first time that there is strong evidence to support the use of self-management interventions to improve long-term outcomes for patients with chronic orofacial pain and TMD. There were significant effects for improvement in long-term pain and depression, the studies were at low risk of bias and there were sufficient numbers of studies that could be pooled to give an overall treatment effect. The quality and certainty of evidence for the main outcome measures (pain and depression) was high using GRADE scores. For other outcome measures the quality of evidence was also high in GRADE despite the heterogeneity observed for these outcomes in the meta-analysis. Self-management interventions therefore also showed significant improvement on activity interference and long term muscle palpation pain.

The descriptive analysis of studies and interventions used showed that all but two of the included studies were on TMD and that self-management interventions for chronic orofacial pain (mainly TMD) include education, physical (jaw posture relaxation) and psychosocial (cognitive, behavioural) self-regulation. Meta-regression showed that biofeedback did not provide additional contribution to effect size. Given that some types of biofeedback, such as masseter EMG biofeedback, require additional expensive equipment, training and particularly time for patients to practise, further evaluation is required on the value of biofeedback in self-management of chronic orofacial pain.

Implications for management of chronic orofacial pain

Overall, the components identified by the review map onto a biopsychosocial intervention model involving both physical and psychological approaches to the management of chronic orofacial pain (mainly TMD). This is not dissimilar to approaches identified for management of chronic back pain (with which TMD co-occurs) and which have been shown to be cost-effective (Hill et al., 2013; Hill et al., 2011; Main et al., 2012).

Physical self-regulation and education as active components for TMD self-management are supported by a Delphi study. It showed that main components of a standard self-care programme of TMD were agreed to comprise education; self-exercise; self-massage; thermal therapy; dietary advice and nutrition; and parafunctional behaviour (Durham et al., 2016a). However it did not include psychological components which were shown to be integral in the management of TMD in our current systematic review. Previous studies using a predominantly psychosocial approach (Goldthorpe et al., 2017) identified the need for physical self-regulation as an additional component. It was not included in their patient manual, but recognised as an important component for management of patients in their trial.

Indeed current recommendations for TMD management (The European Pain Federation) state that physiotherapy and pain management psychology can be useful. This is in agreement with the descriptive components of self-management interventions identified in our review that show packages of both physical and psychosocial components appear beneficial. Future research needs to explore how these approaches interact separately and / or combined in a single intervention. Indeed this can have implications for pain management programmes including those for orofacial pain which tend to address physical and psychosocial management separately e.g. by referral to a physiotherapist and /or clinical psychologist. It may be that such interventions delivered as a package by skilled clinicians using a biopsychosocial approach may be more appropriate. Indeed it has been found to be effective for physiotherapists to deliver a self-management package (comprising education, physical and psychosocial components) for biopsychosocial management of back pain (Hill et al., 2013; Hill et al., 2011; Main et al., 2012). Both future trials and current pain management programmes for chronic orofacial pain and TMD should prioritise a biopsychosocial approach that includes education, physical and psychosocial components. Indeed self-reports of jaw parafunction, psychosocial factors and reporting of other somatic symptoms have been shown to be the strongest predictors of TMD the large prospective OPERRA study (Slade et al., 2007; Slade et al., 2016). These risk factors lend themselves to the biopsychosocial approach identified by the findings of the current systematic review.

It is important to note that the trials included in the current review were mainly on TMD. The physical self-regulation (jaw posture relaxation) component is therefore relevant to TMD alone rather than all facial pain subtypes as TMD is commonly associated with parafunctional habits (Durham et al., 2016a). Future research needs to explore the effects of self-management on all facial pain subtypes as per the study by Goldthorpe et al., (2017) and determine whether physical self-regulation components are effective for other subtypes of chronic orofacial pain.

Implications for future research

The studies eligible for inclusion in this review were conducted in secondary care where patients had developed long-standing chronic orofacial pain. Given the effectiveness of self-management in this group of patients, future studies need to be conducted in primary care to explore whether early intervention can improve outcome by preventing chronicity. This certainly appears to be the case for early intervention in tertiary care (Gatchel et al., 2006). Future trials also need to standardise outcome measures so that they can be comparable across trials. In the current review, we were able to compare effectiveness for pain intensity and physical and emotional functioning using outcomes available in the included trials. Of these, only outcomes for pain intensity and emotional functioning (depression was the only outcome across trials that was measured) could be pooled in the meta-analysis. Physical functioning represented by activity interference could not be pooled due to high heterogeneity. Outcome measures for these domains (pain intensity, physical and emotional functioning) need to be standardized for future trials so that results can be compared across trials and pooled for meta-analyses. Core outcome measures for chronic pain in clinical trials have been clearly defined by initiatives such as IMMPACT and these would appear to be an appropriate benchmark (Turk et al., 2008) for future trials on chronic orofacial pain and TMD. Indeed there are several dimensions of emotional functioning like fear of pain, catastrophizing and anxiety that are relevant to pain management but due to the lack of homogeneity in their measurement we were unable to assess their effects.

Future work that explores the mechanisms by which these interventions bring about change is also needed to inform outcome measures. For example, Turner et al (Turner et al., 2007) examined potential mediators, moderators and predictors of patient improvement with CBT. It was a novel study that examined whether pre to post treatment process variable changes mediated CBT effects on subsequent outcomes (Turner et al., 2007). The results showed that change in perceived pain control and self-efficacy were important in explaining the treatment effects of CBT on the outcomes and should be considered in designing future behavioural interventions for TMD. A further study by Litt (Litt et al., 2010) also showed that somatization, self-efficacy and readiness for treatment were significant moderators. Work by our group assessed processes of engagement with a self-management intervention and this showed that key mechanisms of change centred around: identification with the intervention; feeling believed and understood; obtaining a plausible explanation for symptoms; degree of perceived effort required to engage; acceptance of having a long-term condition; and receiving demonstrative, positive feedback (Goldthorpe et al., 2016b). These studies indicate that self-efficacy, pain control, and understanding and accepting the chronicity of the conditions are important biopsychosocial predictors of patient improvement and should be incorporated into future interventions. This is similar to other chronic pain conditions like chronic back pain whereby mediators like obtaining a plausible explanation for symptoms and knowledge of the condition have led to the development of public health approaches (Roland et al., 2002; Waddell and Moffett 2004; Williams et al., 2009). Such approaches need to be considered for chronic orofacial pain and TMD and indeed specific self-management advice can be included in both primary care dental and medical practices. Over the counter pain relief (non-steroidal anti-inflammatory drugs) are particularly useful for TMD pain and can be incorporated into self-management plans. This will avoid the need for costly invasive and irreversible procedures like surgery, occlusal rehabilitation and splints.

Quality of the evidence in the review and comparison to previous reviews

The risk of bias pertaining to each item discussed in the results section was low for the majority of domains used in the assessment. The GRADE scoring showed that the certainty of evidence was high for all the outcome measures. Therefore the quality of the evidence was high for trials included in the review. The component analysis showed that all trials included self-management and physical and psychosocial self-regulation. Only six studies included biofeedback for which we were able to conduct a meta-regression. This showed that biofeedback alone does not produce an effect in the meta-regression model with very low residual heterogeneity (I^2 = 7%).

The results of the current review update the findings of our previous Cochrane systematic review (Aggarwal et al., 2011) which showed that psychosocial interventions were effective in improving long term outcomes for patients with chronic orofacial pain. However that review failed to acknowledge the importance of the components within the interventions and grouped all interventions into a psychosocial group. In addition the evidence was weak as few studies were included and an overall quality assessment of the quality of evidence was not conducted. Other systematic reviews in this area (Liu et al., 2012; Randhawa et al., 2016) have suffered from methodological shortcomings due to the limited amount of studies, lack of meta-analysis and including interventions with a number of disparate components all of which have led to inconclusive findings.

Potential biases

Given that the majority of interventions were delivered by a therapist, bias arising from therapeutic alliance related to the quality of doctor-patient relationship may be present which can drive non-specific effects (placebo Effect in clinical practice, and Hawthorne effect in clinical studies). Further, included studies were conducted in tertiary care settings which specialised in the management of chronic orofacial pain. This may affect the generalizability of the results as patients in these settings are likely to represent the more severe and intractable cases of chronic orofacial pain and hence share common characteristics. Future trials need to explore early management of chronic orofacial pain in primary care using these interventions. Whist we concluded that overall risk of bias was low and indeed trials by Turner et al., (2006) and Shedden-Mora et al., (2013) were completely free of the domains of bias assessed, data permitting, we would have used sensitivity analyses to examine the effect of concealed allocation, intention-to-treat analysis and blind outcome assessment on the overall estimates of effect.

CONCLUSIONS

The findings of this review provide strong evidence for the use of non-invasive self-management interventions for patients with chronic orofacial pain (mainly TMD). The components of these interventions included physical self-regulation (jaw posture regulation), psychosocial (cognitive and behavioural) self-regulation and education. Future work needs to prioritise the use of these interventions in early management of chronic orofacial pain including TMD.

Author Contributions

Vishal R. Aggarwal: study design, studies selection, data extraction, risk of bias assessment, data analysis and interpretation, drafting the manuscript.

Yu Fu: systematic search in databases, studies selection, data extraction, risk of bias assessment, data interpretation, revising the manuscript.

Chris J. Main: interpretation of data analysis, critique of relevant literature and theory underpinning the introduction and discussion, revising the manuscript.

Jianhua WU: studies selection, data extraction, risk of bias assessment, data analysis and interpretation, revising the manuscript

All authors have read the article, discussed the results and commented on the manuscript.

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TABLE LEGENDS

Table 1 Components of self-management interventions for included studies

Table 2 GRADE analysis showing certainty of evidence for self-management compared to usual care for chronic orofacial pain

Table 3 Effectiveness of self-management compared to usual care for muscle palpation pain and activity interference

Table 4 Sub-group analysis showing effectiveness of self-management for TMD alone

FIGURE LEGENDS

Figure 1 PRISMA flow diagram

Figure 2a Overall risk of bias

Figure 2b Risk of bias for individual studies. Green circles with '+' symbol indicate low risk of bias; yellow circles with '?' symbol indicate unclear risk of bias; red circles with '–' symbol indicate high risk of bias.

Figure 2c Funnel plots for outcomes reported by more than 5 studies. Dots outside the funnel indicate outliers (Egger's test p-values: short term pain = 0.35; long term pain = 0.52; activity interference = 0.34; Long –term depression = 0.69)

Figure 3 Comparison - Any self-management intervention versus usual care Outcome - Pain short term (3months or less)

Figure 4 Comparison – Self- management intervention versus usual care Outcome - Pain long term (greater than 3 months)

Figure 5 Comparison - Any self-management intervention versus usual care Outcome - Depression long term (greater than 3 months)

Study Details	COFP subtype	Self-management		Physical self-regulation			Psychological		Education
		Patient manual	Between session work	Jaw posture relaxation and habit reversal	Bio feedback	Breathing techniques	Cognitive therapy	Behaviour therapy	
Bergdahl 1995	BMS		√				√		
Carlson 2001	TMD	√		√		Diaphragmatic breathing			Patients were instructed to wear the splint at night and were provided with general information regarding etiology and self-care strategies for managing myofascial pain
Crockett 1986	TMD	√	√	√	√			√	
Dworkin 1994	TMD	√	√	√			√	√	
Ferrando 2012	TMD		√				√	√	Psychoeducation
Gardea 2001	TMD	√	√	√	√		√	√	Education of stress and relationship to anxiety, depression and pain
Gatchel 2006	TMD	√	√	√	√		√	√	Education (mind-body relationship to stress and body's reaction to stress)
Goldthorpe 2017	All subtypes	√	√				√	√	
Litt 2010	TMD	√	√	√			√	√	
Shedden-Mora 2013	TMD	√	√	√	√		√	√	Patients were educated about symptoms and causes of their TMD

Townsend 2001	TMD	√	√	√		Deep breathing			
Turk 1993	TMD		√	√	√		√	√	Didactic education on link between stress,muscle tension and pain;
Turk 1996			√	√	√		√	√	Didactic education regarding the association between stress, increased muscle tension, and pain
Turner 2006	TMD	√		√			√	√	
Total		**10**	**12**	**11**	**6**		**11**	**11**	

Table 1 Components of self-management interventions for included studies

Table 2: Certainty of evidence for self-management compared to usual care for chronic orofacial pain

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Anticipated absolute effects	
			Risk with Usual care	Risk difference with Self-management
Pain short term (<= 3 months) assessed with: VA, YF, JW	779 (14 RCTs)	⊕⊕⊕⊕ HIGH	-	SMD 0.06 SD lower (0.22 lower to 0.09 higher)
Pain long term (>3 months) assessed with: VA, YF, JW	757 (12 RCTs)	⊕⊕⊕⊕ HIGH	-	SMD 0.32 SD lower (0.47 lower to 0.17 lower)
Muscle palpation pain long term (> 3 months) assessed with: VA, YF, JW	143 (3 RCTs)	⊕⊕⊕⊕ HIGH	-	SMD 0.58 SD lower (0.92 lower to 0.24 lower)
Activity interference / disability (> 3 months) assessed with: VA, YF, JW	527 (10 RCTs)	⊕⊕⊕⊕ HIGH	-	SMD 0.29 SD lower (0.47 lower to 0.11 lower)
Depression long term (> 3 months) assessed with: VA, YF, JW	524 (8 RCTs)	⊕⊕⊕⊕ HIGH	-	SMD 0.32 SD lower (0.5 lower to 0.15 lower)

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

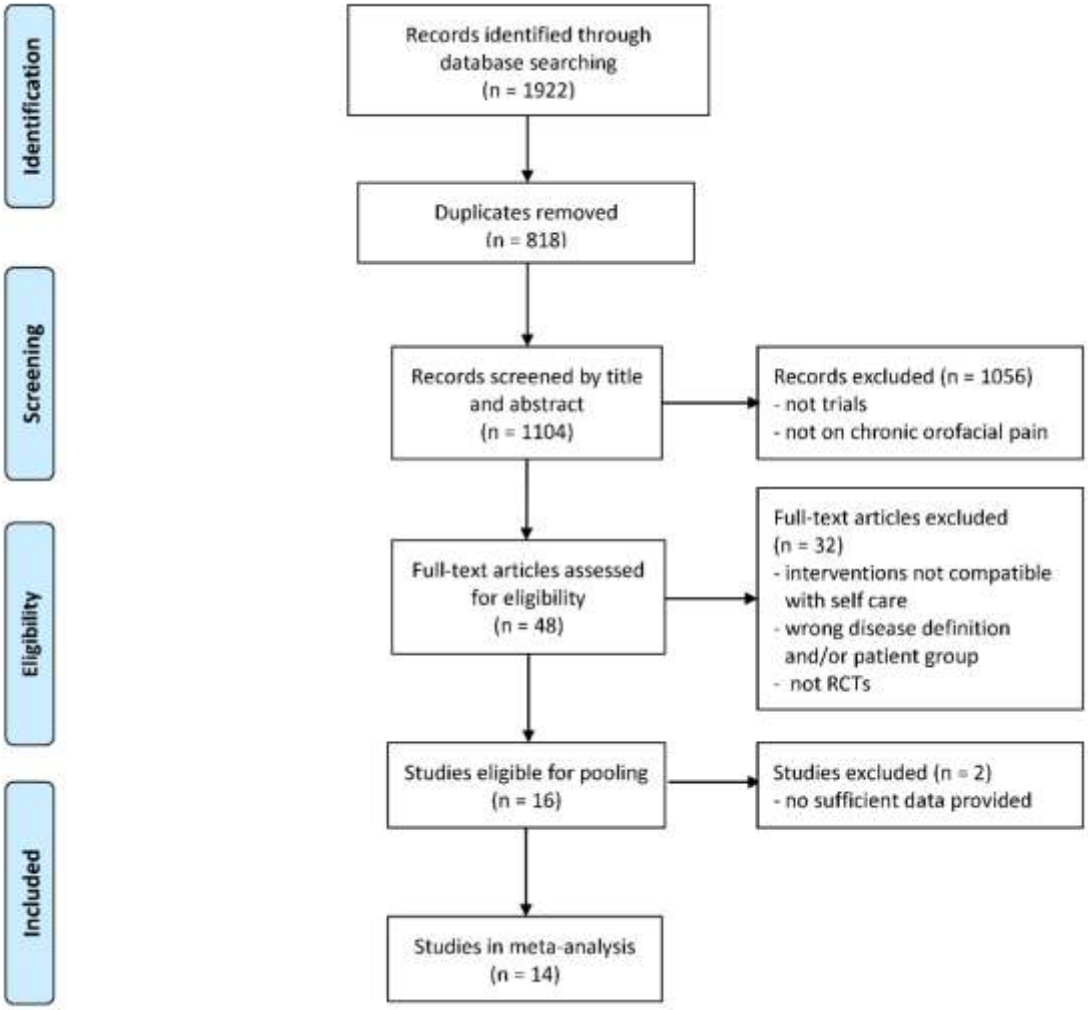
CI: Confidence interval; **SMD:** Standardised mean difference

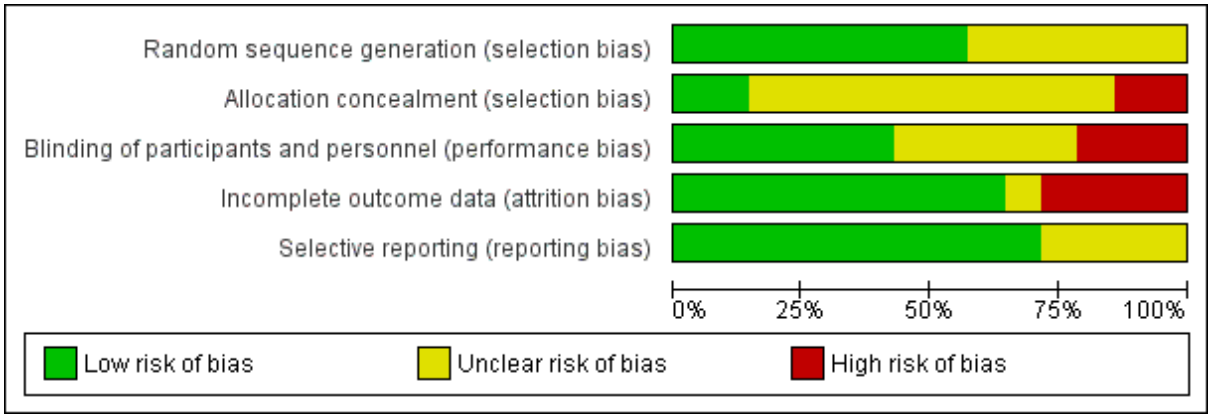
Table 3: Effectiveness of self-management compared to usual care on muscle palpation pain and activity interference

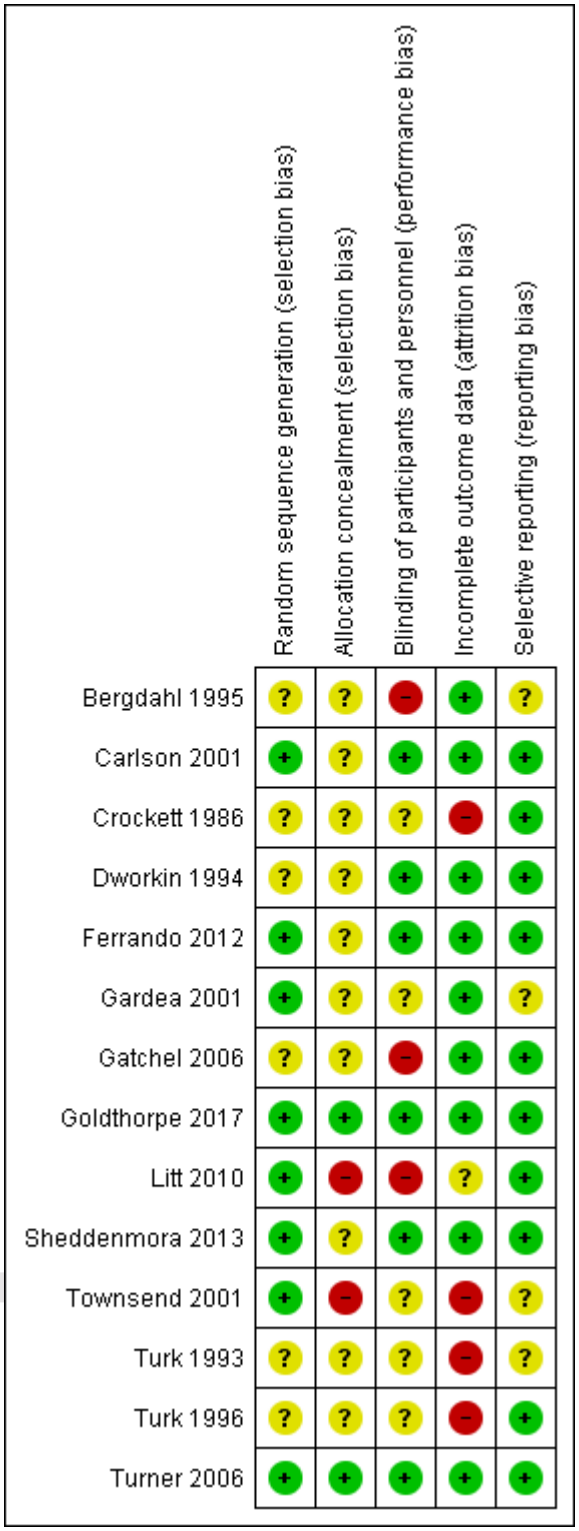
Outcomes	Intervention	Control	No. of studies	Pooled effect	Heterogeneity
Muscle palpation pain (>3 months)	Combined self-care biofeedback and CBT	Usual care	1	-0.39 (-0.91, 0.13)	-
	Self-care CBT	Usual care	2	-0.72 (-1.16, -0.27)	78%
	All intervention	Usual care	3	-0.58 (-0.92, -0.24)	63%
Activity interference/disability **Long term (>3 months)**	Combined self-care biofeedback and CBT	Usual care	2	0.06 (-0.40, 0.52)	0%
	Self-care CBT	Usual care	7	-0.37 (-0.57, -0.16)	85%
	All intervention	Usual care	9	-0.29 (-0.47, -0.11)	79%

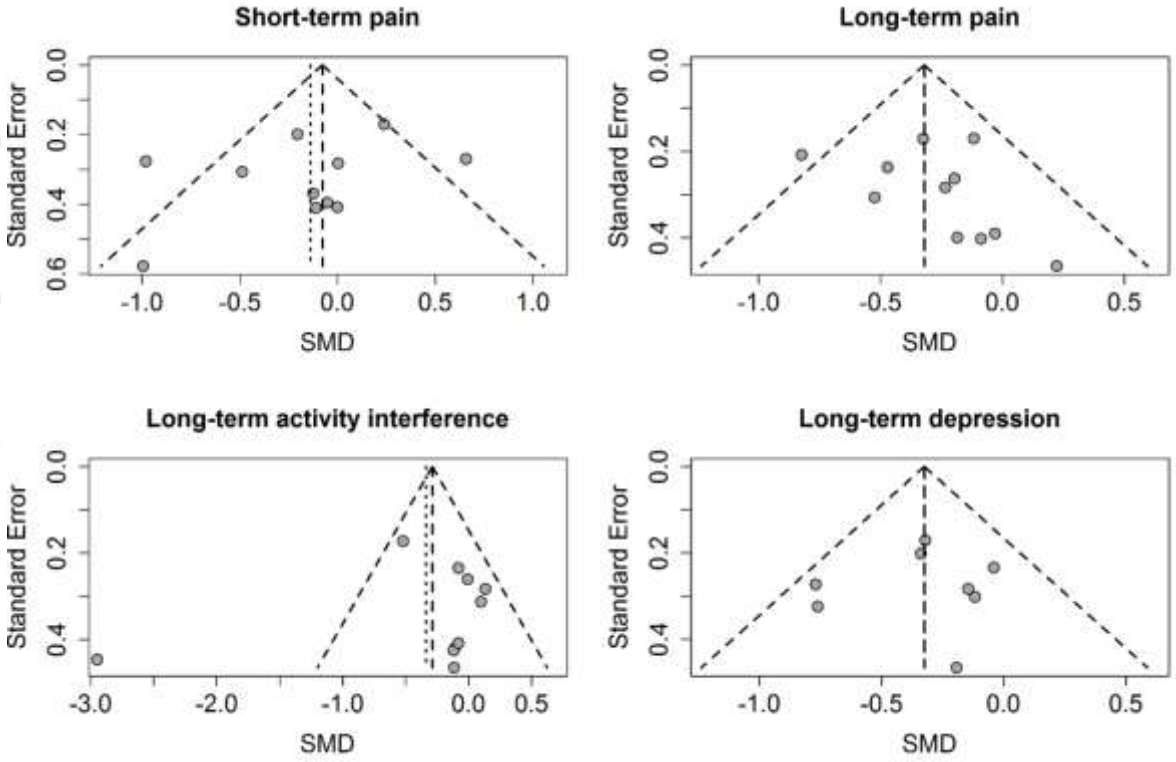
Table 4: Subgroup analysis of effectiveness of self-management for TMD alone

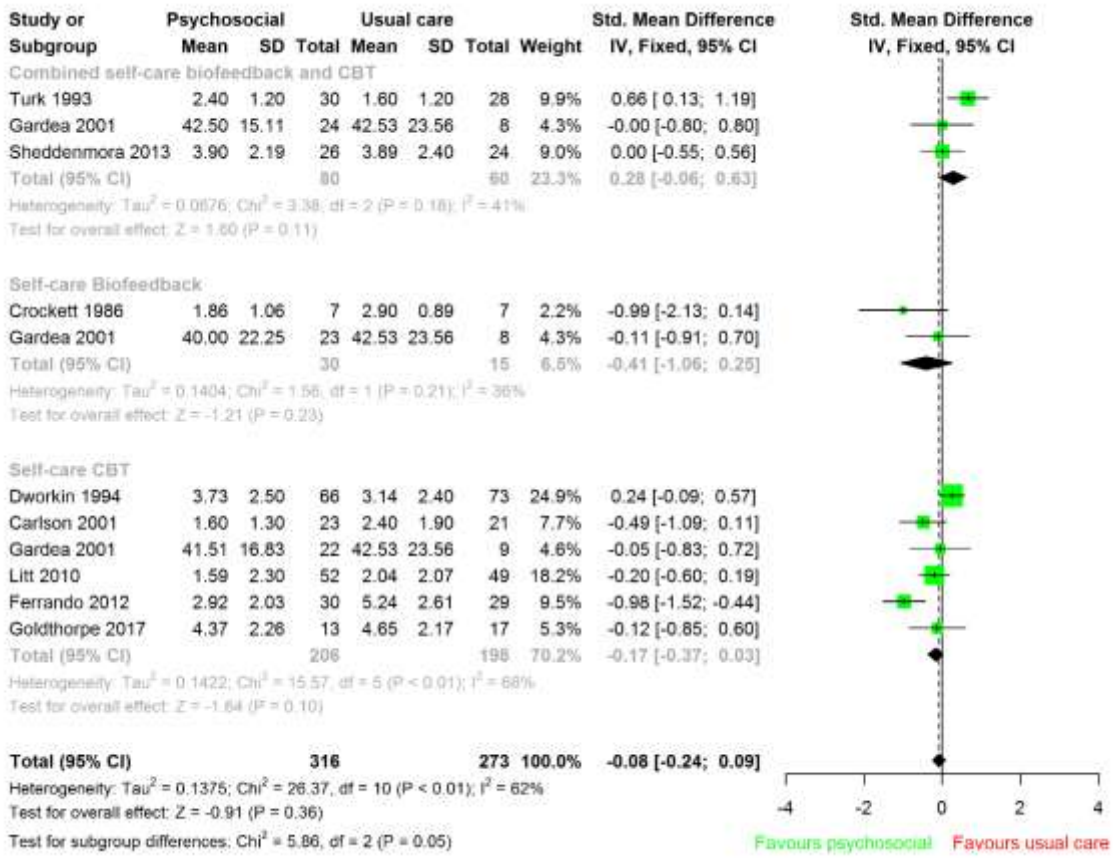
Outcomes	Intervention	Control	No. of studies	Pooled effect	Heterogeneity
Long-term pain	Combined self-care biofeedback and CBT	Usual care	4	-0.46 (-0.72, -0.20)	41.5%
	Self-care CBT	Usual care	5	-0.28 (-0.47, -0.09)	0%
	All interventions	Usual care	9	-0.34 (-0.50, -0.19)	10%
Long-term depression	Combined self-care biofeedback and CBT	Usual care	3	-0.41 (-0.68, -0.13)	26.7%
	Self-care CBT	Usual care	4	-0.28 (-0.51, -0.05)	16.3%
	All interventions	Usual care	7	-0.33 (-0.51, -0.15)	12%

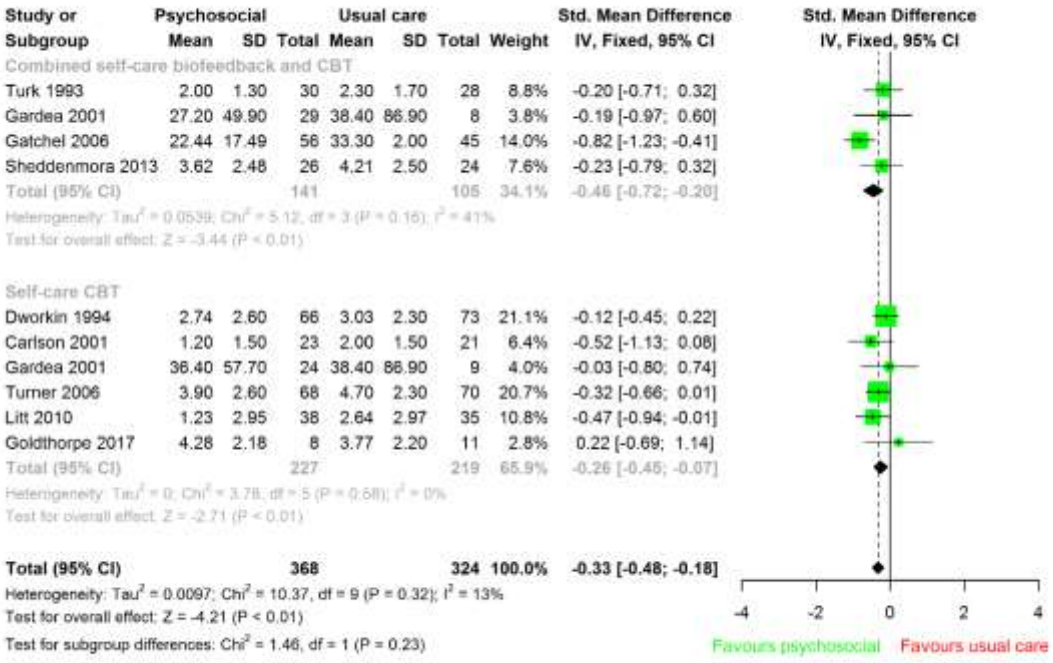


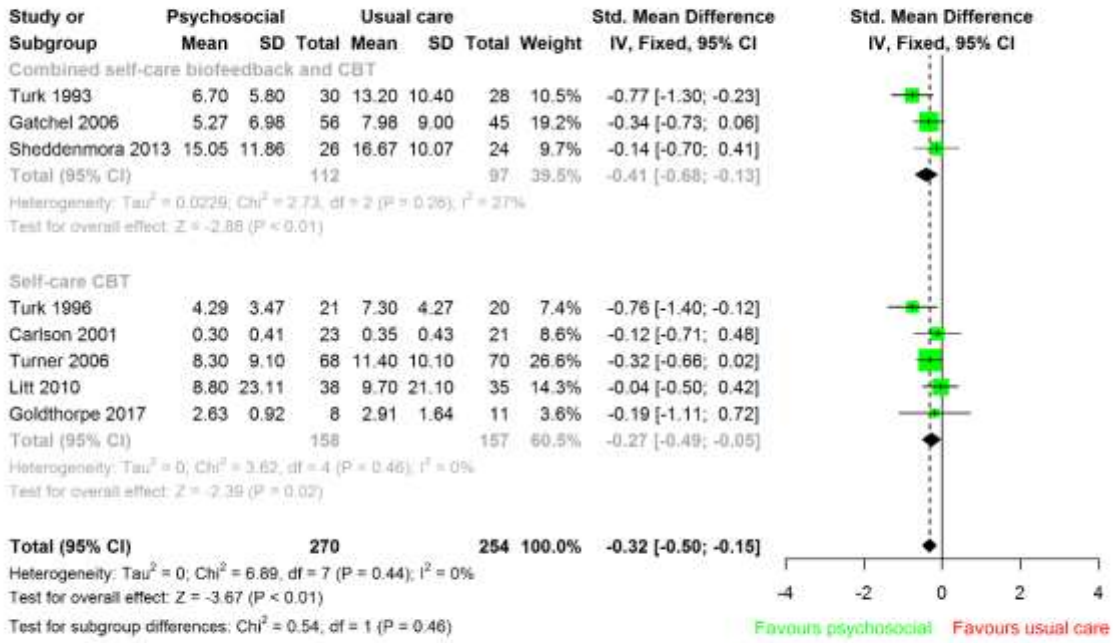












Appendix 1. SEARCH STRATEGY

MEDLINE (OVID) search strategy

1. CRANIOMANDIBULAR DISORDERS/
2. ("temporomandibular$" or "temporo-mandibular").mp.
3. tmj.mp. ortmd.ti,ab.
4. exp MYOFASCIAL PAIN SYNDROMES/
5. (myofascial and (pain$ or disorder$ or dysfunction$)).mp.
6. (myofacial and (pain$ or disorder$ or dysfunction$)).mp.
7. (atypical and odontol$).mp.
8. (atypical and toothache$).mp.
9. (atypical and "tooth pain").mp.
10. "phantom tooth pain".mp.
11. exp Facial Pain/
12. (atypical and "facial pain").mp.
13. (atypical and "facial neuralgia").mp.
14. or/1-14
15. exp BEHAVIOR THERAPY/
16. PSYCHOTHERAPY/
17. AUTOGENIC TRAINING/
18. exp COUNSELING/
19. SOCIAL SUPPORT/
20. ("behaviour therap$" or "behaviortherap$").mp.
21. counsel$.mp.
22. "autogenic train$".mp.
23. (psychotherap$ or psychoanal$).mp.
24. ("self-help group" or "self help group" or communicat$ or educat$ or inform$).mp.
25. or/20-25
36. 15 and 25

The above subject search was linked to the Cochrane Highly Sensitive Search Strategy (CHSSS) for identifying randomized trials in

MEDLINE: sensitivity maximising version (2009 revision) as referenced in Chapter 6.4.11.1 and detailed in box 6.4.c of *The Cochrane*

Handbook for Systematic Reviews of Interventions, Version 5.0.2 [updated September 2009] (Higgins 2011):

1. randomized controlled trial.pt.

2. controlled clinical trial.pt.

3. randomized.ab.

4. placebo.ab.

5. drugtherapy.fs.

6. randomly.ab.

7. trial.ab.

8. groups.ab.

9. or/1-8

10. exp animals/ not humans.sh.

11. 9 not 10

The Cochrane Oral Health Group Register Search Strategy

((“temporomandibular” or “temporo-mandibular” or “myofascial pain*” or “myofacial pain*” or “myofascial disorder*” or “myofacial disorder*” or “myofascial disorder*” or “myofacial disorder*” or toothache or “tooth pain*” or “facial pain*” or “facial neuralgia*” or “persistent idiopathic facial pain*”) AND (“behaviour therap*” or “behaviortherap*” or counsel* or

“autogenic train*” or psychotherap* or psychoanal* or self-help or “self help” or communicat* or inform* or educat*))

Cochrane Central Register of Controlled Clinical Trials (CENTRAL) Search Strategy

#1 MeSH descriptor Craniomandibular Disorders this term only

#2 (temporomandibular* in All Text or temporo-mandibular* in All Text)

#3 (tmj in Title, Abstract or Keywords or tmd in Title, Abstract or Keywords)

#4 MeSH descriptor MYOFASCIAL PAIN SYNDROMES this term only

#5 (myofascial in All Text and (pain* in All Text or disorder* in All Text or dysfunction* in All Text))

#6 (myofacial in All Text and (pain* in All Text or disorder* in All Text or dysfunction* in All Text))

#7 (atypical in All Text and odontol* in All Text)

#8 (atypical in All Text and toothache* in All Text)

#9 (atypical in All Text and "tooth pain" in All Text)

#10 "phantom tooth pain" in All Text

#11 MeSH descriptor Facial Pain explode all trees

#12 (atypical in All Text and "facial pain" in All Text)

#13 (atypical in All Text and "facial neuralgia" in All Text)

#14 (#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14)

#15 MeSH descriptor BEHAVIOR THERAPY explode all trees

#16 MeSH descriptor Psychotherapy this term only

#17 MeSH descriptor AUTOGENIC TRAINING this term only

#18 MeSH descriptor Counseling explode all trees

#19 MeSH descriptor Social Support this term only

#20 ("behaviour therap*" in All Text or "behaviortherap*" in All Text)

#21 counsel* in All Text

#22 "autogenic train*" in All Text

#23 (psychotherap* in All Text or psychoanal* in All Text)

#24 ("self-help group" in All Text or "self help group" in All Text or communicat* in All Text or educat* in All Text or inform* in

All Text)

#25 (#15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24)

#25 (#14 and #25)

EMBASE (OVID) Search Strategy

1. exp CRANIOMANDIBULAR DISORDERS/

2. ("temporomandibular$" or "temporo-mandibular").mp. [mp=title, original title, abstract, name of substance word, subject

heading word]

3. tmj.mp. ortmd.ti,ab. [mp=title, original title, abstract, name of substance word, subject heading word]

4. exp MYOFASCIAL PAIN SYNDROMES/

5. (myofascial and (pain$ or disorder$ or dysfunction$)).mp. [mp=title, original title, abstract, name of substance word, subject

heading word]

6. (myofacial and (pain$ or disorder$ or dysfunction$)).mp. [mp=title, original title, abstract, name of substance word, subject

heading word]

7. (atypical and odontol$).mp.

8. (atypical and toothache$).mp.

9. (atypical and "tooth pain").mp. [mp=title, original title, abstract, name of substance word, subject heading word]

10. "phantom tooth pain".mp.

11. exp Facial Pain/

12. (atypical and "facial pain").mp. [mp=title, original title, abstract, name of substance word, subject heading word]

13. (atypical and "facial neuralgia").mp. [mp=title, original title, abstract, name of substance word, subject heading word]

14. or/1-13

15. exp BEHAVIOR THERAPY/

16. PSYCHOTHERAPY/

17. AUTOGENIC TRAINING/

18. exp COUNSELING/

19. SOCIAL SUPPORT/

20. ("behaviour therap$" or "behaviortherap$").mp. [mp=title, original title, abstract, name of substance word, subject heading

word]

21. counsel$.mp.

22. "autogenic train$".mp.

23. (psychotherap$ or psychoanal$).mp. [mp=title, original title, abstract, name of substance word, subject heading word]

24. ("self-help group" or "self help group" or communicat$ or educat$ or inform$).mp. [mp=title, original title, abstract, name of

substance word, subject heading word]

25. or/15-24

31. 14 and 25

The above subject search was linked to the Cochrane Oral Health Group filter for EMBASE via OVID:

1. random$.ti,ab.
2. factorial$.ti,ab.
3. (crossover$ or cross over$ or cross-over$).ti,ab.
4. placebo$.ti,ab.
5. (doubl$ adj blind$).ti,ab.
6. (singl$ adj blind$).ti,ab.
7. assign$.ti,ab.
8. allocat$.ti,ab.
9. volunteer$.ti,ab.
10. CROSSOVER PROCEDURE.sh.
11. DOUBLE-BLIND PROCEDURE.sh.
12. RANDOMIZED CONTROLLED TRIAL.sh.
13. SINGLE BLIND PROCEDURE.sh.
14. or/1-13
15. ANIMAL/ or NONHUMAN/ or ANIMAL EXPERIMENT/
16. HUMAN/
17. 16 and 15
18. 15 not 17
19. 14 not 18

PsycINFO (OVID) Search Strategy

1. exp Myofascial pain/
2. ("temporomandibular$" or "temporo-mandibular").mp. [mp=title, abstract, heading word, table of contents, key concepts]
3. tmj.mp. ortmd.ti,ab. [mp=title, abstract, heading word, table of contents, key concepts]
4. (myofascial and (pain$ or disorder$ or dysfunction$)).mp. [mp=title, abstract, heading word, table of contents, key concepts]

5. (myofacial and (pain$ or disorder$ or dysfunction$)).mp. [mp=title, abstract, heading word, table of contents, key concepts]

6. (atypical and odontol$).mp.

7. (atypical and toothache$).mp.

8. (atypical and "tooth pain").mp. [mp=title, abstract, heading word, table of contents, key concepts]

9. "phantom tooth pain".mp.

10. (atypical and "facial pain").mp. [mp=title, abstract, heading word, table of contents, key concepts]

11. (atypical and "facial neuralgia").mp. [mp=title, abstract, heading word, table of contents, key concepts]

12. or/1-11

13. exp BEHAVIOR THERAPY/

14. PSYCHOTHERAPY/

15. AUTOGENIC TRAINING/

16. exp COUNSELING/

17. SOCIAL SUPPORT/

18. ("behaviour therap$" or "behaviortherap$").mp. [mp=title, abstract, heading word, table of contents, key concepts]

19. counsel$.mp.

20. "autogenic train$".mp.

21. (psychotherap$ or psychoanal$).mp. [mp=title, abstract, heading word, table of contents, key concepts]

22. ("self-help group" or "self help group" or communicat$ or educat$ or inform$).mp. [mp=title, abstract, heading word, table of

contents, key concepts]

23. or/13-22

27. 23 and 12

The above subject search was linked to the Cochrane Oral Health Group filter for PsycINFO via OVID:

1. exp clinical trials/

2. (clin$ adj25 trial$).ti,ab.

3. placebo$.ti,ab.

4. random$.ti,ab.

5. ((randomised adj controlled adj trial$) or (randomized adj controlled adj trial$)).mp.

6. (controlled adj clinical adj trial$).mp.

7. (random adjallocat$).mp.

8. ((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).ti,ab.

9. (control$ adj4 trial$).mp.

10. (ANIMALS not HUMANS).sh.

11. or/1-9

12. 11 not 10

Characteristics of included studies:

Bergdahl 1995

Methods	Randomised controlled trial conducted in: Sweden Number of centres: 1 Recruitment period: Not stated Funding source: Swedish Dental Society and the Faculty of Odontology, Umed University, Sweden Trial identification number: Not stated	
Participants	30 patients with resistant burning mouth syndrome (BMS) were divided at random into equal groups, the therapy group (TG) and the attention/placebo group (APG). The patients were odontologically and medically examined and treated according to the protocol for the management of patients with BMS, including complete anamnesis, general medical and odontological examination, laboratory investigation and an epicutaneous patch test.	
Intervention	Therapy group (TG) - Phase 1: an introductory session consisting of a motivational input and an oral examination. The patients were given time to decide whether or not to participate in the study. Phase 2: evaluation of BMS intensity (pre-treatment). Phase 3: cognitive therapy (CT) for 12-15 sessions; one hour once a week. Phase 4: evaluation of BMS intensity and oral examination immediately after completed CT (post-treatment). Phase 5: evaluation of BMS intensity and oral examination 6 months after completed CT.(6-month follow-up). Attention/placebo (APG) - Phase 1: an introductory session consisting of a motivational input and an oral examination. The patients were given time to decide whether or not to participate in the study. Phase 2: evaluation of BMS intensity (pre-treatment). Phase 3: return visits 3 times during 12-15 weeks for evaluation of BMS intensity and oral examination. Phase 4: evaluation of BMS intensity and oral examination (post-treatment). Phase 5: evaluation of BMS intensity and oral examination 6 months later (6-month follow-up).	
Outcomes	Intensity of burning mouth measures on a non-validated VAS ranging from 1 to 7 (endurable to unendurable).	
Risk of bias		
Bias	**Authors judgement**	**Support for judgement**
Random sequence generation	Unclear risk	Not mentioned.
Allocation concealment	Unclear risk	Not mentioned.
Blinding (performance bias and detection bias) All outcomes	High risk	All the patients evaluated their burning mouth intensity with the same dentist

Incomplete outcome data (attrition bias) All outcomes	Low risk	There were no drop-outs.
Selective reporting (reporting bias)	Unclear risk	Only intensity measured as an outcome.
Other bias	High risk	Use of non-validated scales to measure outcome. Also components of intervention not described making it difficult to assess what techniques were being used

Carlson 2001

Methods	Randomised controlled trial conducted in: US Number of centres: 1 Recruitment period: Not stated Funding source: Not stated Trial identification number: Not stated	
Participants	23 were assigned to the intervention and 21 were assigned to the control group. Inclusion: participants had to have a primary diagnosis of myofascial pain in the masticatory muscles that was based on guidelines from the Research Diagnostic Criteria for Type 1a and Type 1b disorders and included a chief complaint originating from the masticatory muscles, pain complaint that had been present for longer than 1 month, and report of pain in response to palpation of 3 or more standard muscle sites. All participants were maintained on medications that they were taking prior to the initial evaluation, and initial medication usage was not altered by the treating dentists during the course of the study	
Intervention	Physical self-regulation (PSR) versus standard dental care (SDC). Both interventions had 2 visits (50 mins) 3 weeks apart PSR - targeted 7 specific domains: monitoring and reducing muscle parafunction in the head and neck region, proprioceptive awareness training to improve symmetric head and neck posture, instructions for improving sleep onset, position oriented relaxation training, physical activity, nutrition/fluid management, and training in diaphragmatic breathing (n = 23) SDC - a flat-plane intraoral appliance. Patients were instructed to wear the splint at night and were provided with general information regarding etiology and self-care strategies for managing myofascial pain (e.g. eat soft foods, relax the jaws during the day). Participants were then scheduled for a follow-up appointment in 3 weeks for splint adjustment and reinforcement of the pain management procedures. Participants were also reminded about how to seek further care if they felt that the present protocol was not meeting their needs (n = 21)	
Outcomes	Pain relief measured on VAS (0 to 100). Activity interference, physical examination (mouth opening, muscle pain, awareness of tooth contacts) and psychologic variables (affective distress, somatization, depression, anxiety, obsessive/compulsive, sleep dysfunction, fatigue).	
Risk of bias		
Bias	**Authors judgement**	**Support for judgement**
Random sequence generation	Low risk	Random assignment was accomplished by the use of a table of random numbers
Allocation concealment	Unclear risk	Not mentioned.
Blinding (performance bias and detection bias) All outcomes	Low risk	Only outcome assessment blinded - a board-certified dentist with postdoctoral

		training in orofacial pain who was not aware of the treatment protocol to which each participant was assigned performed all initial dental evaluations and administered the self-report measures after the dental evaluations
Incomplete outcome data (attrition bias) All outcomes	Low risk	Subsequent data analyses of the initial physical and psychologic characteristics of those who dropped out of the study versus those who completed the study did not reveal any significant differences between the 2 groups on measured variables obtained at the beginning of the study
Selective reporting (reporting bias)	Low risk	Negative results have been reported.
Other bias	High risk	Only included a specific patient group pertaining to military personnel

Crockett 1986

Methods	Randomised controlled trial conducted in: Canada Number of centres: 1 Recruitment period: Not stated Funding source: National Health and Welfare grant NAHS 30-9625 and provincial government Youth Employment Program project Trial identification number: Not stated	
Participants	7 were assigned to the dental splint and physiotherapy program, 7 were assigned to the relaxation program utilizing progressive muscle relaxation, biofeedback, and stress management techniques and 7 were assigned to the minimal treatment program involving transcutaneous electrical nerve stimulation. Inclusion: complaint of pain of at least 6 months duration; tenderness to palpation of masticatory muscles; limitation or deviation of jaw mobility; absence of radiographic evidence of pathology of the joint as would result from disease or trauma Exclusion: Joint tenderness or joint sounds may or may not have been present, but were exclusionary criteria if they were the principal complaint or associated with an organic condition. Many of the individuals screened complained of clicking or crepitus in the temporomandibular (TM) joint, which was considered to result from displacement of the articular disc and thus were not included in the study.	
Intervention	3 interventions compared each consisting of 8-weekly, 1-hour sessions accompanied by recommendations for 30 minutes of daily homework: Dental programme (DPT) - delivered by 2 dentists and 3 physiotherapists. Conservative physical intervention, incorporated the use of an occlusal splint and the provision of weekly physiotherapy sessions oriented to the masticatory system with hot/cold applications, postural corrections, the avoidance of chewy foods, and exercise for the jaw. Subjects were to practice jaw exercises 30 minutes daily Biofeedback enhanced progressive relaxation programme (BER) - tape recorded progressive muscle relaxation training program with EMG training. During sessions 6 to 8 biofeedback was provided while patient undertaking nonverbal puzzles. Homework consisted of 30 mins progressive muscles relaxation exercises using audio tape TENS - weekly subthreshold electrical stimulations. Homework consisted of 30min rest period	
Outcomes	Interincisal opening (dentists rating), pain to palpation (dentists rating on a Likert-Scale), global rating of worst pain during 3-weeks post-treatment (self-reporting on a Likert-Scale),), adjectival pain rating (McGill Pain Questionnaire), mean weekly frequency of pain (self-reporting), mean weekly intensity of pain (self-reporting on a Likert-Scale),), EMG measures also reported	
Notes	For the meta-analysis, biofeedback was used as the intervention group and DPT as the control	
Risk of bias		
Bias	**Authors judgement**	**Support for judgement**

Random sequence generation	Unclear risk	Insufficient detail.
Allocation concealment	Unclear risk	Insufficient detail.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Insufficient information with regard to blinding of outcome assessors. Blinding of participants/carers not feasible
Incomplete outcome data (attrition bias) All outcomes	High risk	7/28 participants not included in analysis. Main reason given was time constraints. However, no detail regarding which groups the 7 had originally been allocated to
Selective reporting (reporting bias)	Low risk	Relevant outcomes covered.
Other bias	High risk	No power calculations, numbers in each group were small and no information on which groups had drop-outs

Dworkin 1994

Methods	Randomised controlled trial conducted in: US Number of centres: 1 Recruitment period: Not stated Funding source: NIDR Trial identification number: Not stated
Participants	95 were assigned to the cognitive behavioural intervention and 90 were assigned to the usual treatment (UT) group. Inclusion: participants had TMD with a self-report of facial ache or pain in the muscles of mastication, the TM joint, the region in front of the ear or inside the ear, other than infection. Exclusion: pain attributable to confirmed migraine or head pain condition other than tension headache; acute infection or other significant disease of the teeth, ear, eye, nose or throat; or history of significant or debilitating chronic physical or mental illness. Patients requiring emergency TMD treatment were also excluded from the study
Intervention	Cognitive behavioural therapy (CBT) (n = 95) versus usual treatment (UT) (n = 90) CBT - brief with 2 group sessions, 2-hours long, spaced 1-week apart. A detailed manual and set of materials to provide information concerning the nature and typical course of TMD; biomedical and biobehavioral management of TMD; the relationships among jaw muscle fatigue, muscle tension, and the psychophysiologic aspects of stress; the basics of pain physiology with an emphasis on chronic pain; how to self-monitor TMD signs and symptoms; and an introduction to cognitive and behavioral pain and stress coping strategies. Patients learned and had an opportunity to briefly practice a progressive relaxation method and a simple physiotherapy exercise for jaw muscles. Delivered by dentists and psychologists UT - conservative and typically included use of flat-plane occlusal splints, non-steroidal anti-inflammatory medications, passive and active range of jaw motion exercises, modification of parafunctional and/or dietary habits and regular use of cold and heat packs. No limitations on number of sessions
Outcomes	Characteristic pain, pain interference, maximum assisted mandibular opening, unassisted mandibular opening, SCL-90 depression, SCL-90 somatization, knowledge of TMD, post-treatment satisfaction
Notes	

Risk of bias

Bias	**Authors judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Block randomisation used but details not described.
Allocation concealment (selection bias)	Unclear risk	Insufficient detail.
Blinding (performance bias and		Outcome measurement blinded - quote: "All clinical and self-report data were gathered at baseline and at 3- and 12-month follow- up by

detection bias) All outcomes	Low risk	dental hygienist examiners blind to the subjects original random assignment to the CB or UT study conditions."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "All subjects who dropped out from the study prior to completion of the 12-month follow-up were asked to complete an abbreviated questionnaire inquiring into the status of their pain and jaw function in order to allow intent to treat analyses of all subjects."
Selective reporting (reporting bias)	Low risk	Relevant outcomes covered.
Other bias	Low risk	Power calculations included and attempts made to standardise delivery of intervention and rotate clinicians delivering it. Also outcome measures collected by blinded personnel.

Dworkin 2002a

Methods	Randomised controlled trial conducted in: US Number of centres: 1 Recruitment period: Not stated Funding source: NIDCR Trial identification number: Not stated	
Participants	61 were assigned to the self-care intervention (SC) and 63 were assigned to the usual care (UC). Inclusion: self-report of facial ache or pain in the muscles of mastication, the TMJ, the region in front of the ear or inside the ear, or report of stiffness or other symptoms of discomfort in the same orofacial region for which usual care was prescribed by the clinic TMD specialist; RDC/TMD Axis II GCP score of 0, I or II-Low; age 18 to 70 years." Exclusion: pain attributable to confirmed migraine or head pain condition other than tension headache; acute infection or other significant disease of the teeth, ears, eyes, nose, or throat; or presence of significant or debilitating chronic physical or mental illness; necessity for emergency TMD treatment."	
Intervention	Self-care intervention (SC) (n = 61) versus usual care (UC) (n = 63) SC - components included: education on TMD, guided reading with structured feedback, relaxation and stress management training including training in abdominal breathing, general muscle relaxation methods, and specific methods for relaxation of head, neck, and masticatory muscles, stress management, self-monitoring of signs and symptoms, development of a "Personal TMD Self-Care Plan", supervised practice and reinforcement of dentist prescribed self-care treatments, maintenance and relapse prevention UC- conservative treatment included: physiotherapy, patient education concerning parafunctional oral behaviours, diet, nature of the condition, and rationale for treatment, medications including analgesics, muscle relaxants, and antidepressants, intraoral flat plane occlusal appliances	
Outcomes	Characteristic pain intensity, pain-related activity interference, vertical jaw range of motion, number of extra-oral muscle palpations, SCL-90 depression, SCL-90 somatization, number of dental visits, helpfulness and satisfaction	
Notes	Usual care included aspects of education and counselling and one may argue that these are psychosocial. However, these are invariably delivered as part of intraoral occlusal plane therapy and the education associated with these is usually directed towards occlusal aetiologies for the condition rather than psychosocial	
Risk of bias		
Bias	**Authors judgement**	**Support for judgement**
Random sequence generation	Unclear risk	Insufficient detail.
Allocation concealment	Unclear risk	Insufficient detail.

Blinding (performance bias and detection bias) All outcomes	High risk	Some outcome measures were self-reported but unsure whether examiners were blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	Participants asked to give minimum data on pain characteristics and drop-outs compared with those who participated
Selective reporting (reporting bias)	Low risk	Relevant outcomes covered.
Other bias	Low risk	Power calculation provided and delivery of intervention standardised using manual and appropriate training

Dworkin 2002b

Methods	Randomised controlled trial conducted in: US Number of centres: 1 Recruitment period: Not stated Funding source: NIDCR Trial identification number: Not stated	
Participants	59 were assigned to the comprehensive care (CC) and 58 were assigned to the usual treatment (UT). Inclusion: self-report of facial ache or pain in the muscles of mastication, the TMJ, the region in front of the ear or inside the ear; RDC/TMD Axis II GCP score of II-High,III or IV; age 18 to 70 years." Exclusion: pain attributable to confirmed migraine or head pain condition other than tension headache; acute infection or other significant disease of the teeth, ears, eyes, nose, or throat; debilitating physical or mental illness; necessity for emergency TMD treatment; inability to speak or write English."	
Intervention	CC - CBT-based programme for chronic pain adapted for TMD and included: behavioural/relaxation, cognitive coping, explanatory model, health care, personal plan, maintenance and relapse prevention UT- conservative treatment included: physiotherapy, patient education concerning parafunctional oral behaviours, diet, nature of the condition, and rationale for treatment, medications including analgesics, muscle relaxants, and antidepressants, intraoral flat plane occlusal appliances	
Outcomes	Characteristic pain intensity, pain-related activity interference, ability to control pain, vertical jaw range ofmotion, number of extraoralmuscle palpations, SCL-90 depression, SCL-90 somatization, helpfulness and satisfaction	
Notes		
Risk of bias		
Bias	**Authors judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Insufficient detail.
Allocation concealment (selection bias)	Unclear risk	Insufficient detail.
Blinding (performance bias and detection bias) All outcomes	Low risk	Outcomes blinded - quote: "All clinical baseline and follow-up study data collection were performed by calibrated and reliable clinical examiners not participating in the RCT and blinded to the study group to which patients were assigned."
Incomplete outcome data (attrition bias)	Low risk	Quote: "All patients who dropped out from the study prior to completion of the 12- month follow-up were asked to provide minimal data about pain and pain-related interference to

All outcomes		allow intent-to-treat analyses."
Selective reporting (reporting bias)	Low risk	Relevant outcomes covered.
Other bias	Unclear risk	Insufficient detail.

Ferrando 2012

Methods	Randomised controlled trial conducted in: Spain Number of centres: 1 Recruitment period: Not stated Funding source: The Spanish Ministry of Science and Technology and the Valencian Regional Government of Industry, University and Science. Trial identification number: Not stated	
Participants	41 were assigned to the experimental group and 31 were assigned to the control group. Inclusion criteria: TMD muscular subgroup diagnosis (group 1 axis I diagnosis) following Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD).The Intellectual ability to follow the evaluation process and psychologic intervention. To assess this, the patient's fluency and ability to understand during the interaction with the doctor together with the diagnosis of a mental disability was considered. Exclusion criteria: abnormalities such as facial deformity, tumoral pathology, lesions of oral mucosa, signs of schizophrenia or other psychotic disorders.	
Intervention	The objective of this study was to assess the efficacy of cognitive behavioural therapy including hypnosis in patients with TMDs with a muscular diagnosis. Participants were randomly assigned to two groups; the experimental group receiving 6 sessions of CBT programme and the control group. All patients received conservative standard treatment for TMD. Assessment for pain variables and psychologic distress were carried out pre-treatment, post treatment (3 months after pre-treatment) and follow up (9 months after pre-treatment).	
Outcomes	Number of painful points on pressure (RDC/TMD), pain frequency (painful days in past 2 months), self-medication frequency (days with self-medication use in past 2 months), subjective pain index (McGill Pain Questionnaire and MPQ), pain interference (MPI), pain severity (MPI), emotional distress (including sub dimensions anxiety, somatization and depression) (BSI).	
Notes		
Risk of bias		
Bias	**Authors judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Quote: "An external statistical program assigned a number (between 0 and 9,999) to the subject included in the research sample: In this case, when the number was between 0 and 5,549, the patient was assigned to the experimental group, the rest (between 5,550 and 9,999) to the control group, compensating for the expected drop-out rate of 25% in the experimental group."

Allocation concealment	Unclear risk	Not stated.
Blinding (performance bias and detection bias) All outcomes	Low risk	Quote: "Outcome assessors were blinded."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "3 drop-outs from right after inclusion were not analysed while others who provided data were included. 'Furthermore, in the control group three patients withdrew (one after one session and two after three sessions) because they did not feel any benefit of the treatment. These patients completed questionnaires after their last session of treatment and were therefore included in the analysis."
Selective reporting (reporting bias)	Low risk	No evidence of selective reporting.
Other bias	Unclear risk	Not stated.

Gardea 2001

Methods	Randomised controlled trial conducted in: United States Number of centres: 1 Recruitment period: Not stated Funding source: National Institutes of health Trial identification number: Not stated
Participants	A total of 108 chronic TMD patients (seeking treatment for symptoms present at least 6 months) were evaluated and randomly assigned to one of four treatment conditions: biofeedback (n D 27), CBST (n D 24), combined biofeedback and CBST (n D 29), or no-treatment comparison (n D 28). Inclusion: all subjects were diagnosed as having TMD, using the RDC criteria. Exclusion criteria eliminated individuals with a significant physical condition such as cancer, low-back pain and fibromyalgia, people with six or more DSM-IV Axis I diagnoses, a diagnosis of psychosis or active suicidal ideation, and those who did not meet the RDC criteria.
Intervention	4 intervention groups: biofeedback (n = 27), CBT (n = 24), combined biofeedback and CBT (n = 29) versus usual care (n = 28) Biofeedback - 12 x 1-2 hour sessions. Standardized protocol developed by one of the authors who specialized in biofeedback and stress management techniques. The equipment consisted of 'AJ & J (Poulsbo, WA), Model M-57 EMG, and the J & J Model T-68 Temperature Biofeedback Units'. The 12 biofeedback sessions included relaxation training and 15 min of temperature and EMG biofeedback. The EMG biofeedback electrodes placement was over the frontalis muscles CBT - 12 x 1-2 hour sessions delivered by clinical psychologists. The protocol was a modified adaptation of a CBT programme for depression and aspects from other pain management programs were also integrated. Topics included a "rationale for skills training, relaxation training, distraction techniques, designing a self-change plan, pleasant activities scheduling, formulating a pleasant activity plan, cognitive restructuring, self-instructional training, social skills training including assertiveness, maintenance of skills, and the development of a life plan". Education of stress and relationship to anxiety, depression and pain was deployed Combined CBT and biofeedback - the combined treatment protocol was a combination of components from the above protocols. While there was some overlapping of material, such as relaxation training, social learning conceptualizations, and maintaining social skills, the 12 sessions for the combined intervention required extra time (approximately 2.5 versus 2 hrs) Usual care - "standard nonsurgical dental care-only group (e.g. treatment involving splints, medication, physical therapy, etc) that controlled for therapeutic contact and expectancy in terms of going through comprehensive biopsychosocial evaluations and questioned about any therapeutic improvements". Number of sessions not stated
Outcomes	Pain (CPI), disability (GCPS) and limitation in mandibular functioning (a brief 12-item checklist).
Notes	Workbooks, reading, homework between sessions. Sessions carried out in sequence order (even if a session missed) Audiotape made of all treatment sessions to ensure consistency and competency

	Follow-up of Mishra 2000; original study based on n = 84.	
Risk of bias		
Bias	**Authors judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	The urn method of randomisation was used which was defined as "a semi random procedure to maintain demographic variables and chronic TMD type (i.e. RDC Axis I physiological diagnostic subgroups) comparable among the treatment groups" Quote: "Method promotes ongoing balance among groups for possible mediating/ confounding variables; in this study these were gender, age, race, initial pain severity, RDC Axis I diagnosis, and DSM-IV diagnosis."
Allocation concealment (selection bias)	Unclear risk	Not stated.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Insufficient detail.
Incomplete outcome data (attrition bias) All outcomes	Low risk	The analysis was weighted by the number of weeks the subject came to treatment. The no-treatment group was only scheduled for a pre- and postevaluation, so those subjects received a weighting of either a 0 (if they did not have a postevaluation) or a 12 (if they did have a postevaluation). However, because all no-treatment group subjects had pre- and post-treatment evaluations, only the weighting factor of 12 was used. Planned pair wise contrasts were conducted to compare the groups to one another.
Selective reporting (reporting bias)	Unclear risk	Insufficient detail.
Other bias	High risk	The combined biofeedback and CBT arm had longer sessions than the other two arms and this may explain the greater improvement

Gatchel 2006

Methods	Randomised controlled trial conducted in: United States Number of centres: 1 Recruitment period: Not stated Funding source: National Institutes of health Trial identification number: Not stated
Participants	56 were assigned to the early intervention which included individual CBT/BFB and 45 were assigned to the control group. Inclusion: adults aged 18 to 70 years who had acute jaw or facial pain that had been present for less than six months. Exclusion: subjects if they had a comorbid pain-exacerbating physical condition (such as cancer or fibromyalgia) or a history of jaw pain before the most recent episode.
Intervention	Early CBT intervention (n = 54) versus non-intervention control (NI) (n = 45) CBT - 6 x 1 hr audiotaped face to face sessions based on previous studies by Gardea 2001. • CBT programme for depression used for CBT •Education (mind-body relationship to stress and body's reaction to stress) • Relaxation training • Distraction and pleasant activity scheduling • Cognitive restructuring • Self-instruction training • Maintenance of skills • Biofeedback delivered to frontalis muscles NI - although treatment not stated authors include a statement "During the entire study, we encouraged all of the subjects, even those in the NI group, to continue treatment as usual with their outside health care providers if needed; we provided no other advice". The types of health care provider consulted by the NI group consisted of chiropractor (13.6 visits), dentist (34.8 visits), massage therapist (13.0 visits), physician (7.6 visits) , medical technician (0.5 visits), oral surgeon (7.1 visits), orthodontist (8.0 visits) and physical therapist (7.7 visits). This suggests that the treatments for this group included a combination of splints, drug therapy and relaxation therapy that would normally be provided by these practitioners
Outcomes	Pain, depression, ways of coping. Measures included a shortened version of the RDC evaluation, BDI-II, the ways of coping, the SCID-I and SCIDII, and a pain intensity measure (CPI).
Risk of bias	
Bias	

Random sequence generation (selection bias)	**Authors judgement**	**Support for judgement**
Allocation concealment (selection bias)	Unclear risk	Not stated.
Blinding (performance bias and detection bias)All outcomes	Unclear risk	Not stated.
Incomplete outcome data (attrition bias) All outcomes	High risk	Only one assessor used to measure outcomes due to scheduling problems and not clear whether blinded
Selective reporting (reporting bias)	Low risk	Quote: "To manage missing data, we used the last-observation-carried-forward approach in which missing values are replaced with the last previous non-missing value. We found no statistical differences between those subjects who completed the one-year follow-up (n = 98) and those who did not (n = 3)."
Other bias	Low risk	Relevant outcomes considered.
	Unclear risk	Only one assessor used to measure outcomes due to scheduling problems and not clear whether blinded. Also, the intervention group has a greater number of visits to a chiropractor, massage therapist and acupuncturist compared with the non-intervention group and this was not adjusted for in the analysis and may suggest that these additional interventions may explain some of the observed improvements in this group

Goldthorpe 2017

Methods	Randomised controlled trial conducted in: UK, TMD and oral medicine clinics of the University of Manchester Dental Hospital and the maxillofacial outpatient clinic at North Manchester General Hospital and Salford Royal NHS Trust Number of centres: 1 Recruitment period: Not stated Funding source: Clinician Scientist Award by the NIHR (cs/2008/08/001) Trial identification number: Not stated
Participants	19 were assigned to the intervention group and 18 were assigned to the usual treatment. Inclusion criteria: Adults aged 16 and over, Those who are suffering from persistent pain in their face or mouth for 3 months or longer, sufficient level of English to complete questionnaires and take part in the guided self-help therapy Exclusion Criteria: Current treatment with a psychological therapy for oral or facial pain, Current suicidal ideation (assessed at baseline by the Patient Health Questionnaire (PHQ-9), Commencement of a prescribed dose of antidepressants less than 3 months prior to the recruitment date
Intervention	Objective of study was to compare treatment with self-guided help against usual treatment. They were randomized into either the intervention group or the usual treatment (control) group Intervention was delivered through manual guided self-help (https://www.click2go.umip.com/i/coa/chronic_orofacial_pain_manual.html) by presenting a series of four steps, starting with understanding and legitimizing chronic orofacial pain by using patient experiences and stories and continuing with three further steps on goal setting, choosing the intervention, and techniques. The manual also included recovery stories to illustrate the techniques described. Techniques focused on three cognitive behavioural interventions: lifestyle changes (managing sleep, irritability, fatigue, and other unhelpful habits; eg, teeth clenching), behavioural activation (increasing or decreasing activities, choosing a balance of routine pleasurable and necessary activities during the week), and cognitive restructuring (identifying and evaluating unhelpful thinking styles). Usual care comprised oral splints, pharmacologic treatment, or counselling and education. These were provided alone or in combination. Validated outcome measures were used to measure the potential effectiveness of the intervention over a number of domains, physical and mental functioning, anxiety and depression, pain intensity and interference with life, disability, and illness behaviour. Bootstrap confidence intervals were computed for the treatment effect post treatment and at three months follow up.
Outcomes	Physical and mental functioning (SF36), anxiety and depression (HADS), pain intensity and interference with life (BPI), disability (MOPDS), illness behaviour (IPQr).

Risk of bias

Bias	**Authors judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Not stated

Allocation concealment (selection bias)	Low risk	Minimization randomization
Blinding (performance bias and detection bias) All outcomes	Low risk	Single blind (impossible to blind patients due to the nature of the treatment but the research who was blind to allocation collected follow up data)
Incomplete outcome data (attrition bias) All outcomes	Low risk	Per protocol
Selective reporting (reporting bias)	Low risk	No evidence of selective reporting
Other bias	Unclear risk	Not stated

Komiyama 1999

Methods	Randomised controlled trial conducted in: Japan Number of centres: 1 Recruitment period: Not stated Funding source: Not stated Trial identification number: Not stated
Participants	20 were assigned to the CB intervention (IT-1), 20 were assigned to the CB intervention with a posture correction in daily life (IT-2). And 20 were assigned to the non-intervention control group (CT). Inclusion: myofascial pain with limited opening (MLO) was defined as "Pain of muscle origin, including a complaint of pain as well as pain associated with localized areas of tenderness to palpation in muscle. Report of pain or ache in the jaw, temples, face, preauricular area, or inside the ear at rest or during function; pain reported by the subject in response to palpation of three or more of the following 20 muscle sites (right side and left side count as separate sites for each muscle): posterior temporalis, middle temporalis, anterior temporalis, origin of masseter, body of masseter, insertion of masseter, posterior mandibular region, submandibular region, lateral pterygoid area, and tendon of the temporalis. At least one of the complaints of pain; plus 3. Pain-free unassisted mandibular opening of less than 40 mm; plus 4. Maximum assisted opening (passive stretch) of 5 mm or greater than, pain-free, unassisted opening." Exclusion criteria: "Patients who have already been treated at other clinics for TMD. Exclusion: patients who have obvious occlusal interference or prostheses of broad area. History of orthodontic treatment. Metabolic disease (e.g. diabetes, hyperthyroidism). Neurological disorders (e.g. dyskinesia, trigeminal neuralgia). Vascular disease (e.g. migraine, hypertensions). Neoplasia. History of drug abuse. Recent facial or cervical trauma (e.g. whiplash). Patients assigned to categories III and IV or answered 'yes' to the questionnaire under psychiatric disorders on the Cornell Medical Index. Patients currently receiving medication or other treatment that could not be interrupted for the study."
Intervention	Cognitive behavioural (CB), CB with posture correction versus non-intervention control group; 20 in each group CB - was carried out in accordance with Dworkin 1994 i.e. information concerning the nature and typical course of MLO; biomedical and biobehavioural management of MLO; the relationship among jaw muscle fatigue, muscle tension, and the psychophysiologic aspects of stress; the basics of pain physiology with an emphasis on chronic pain; how to self-monitor MLO signs and symptoms; and an introduction to cognitive and behavioural pain and stress coping strategies. Patients learned and had an opportunity to briefly practice a progressive relaxation method for the jaw muscles. The patients were given these instructions at each monthly appointment for 12 months CB with posture correction - in addition to the above subjects were asked to do the following: "(A) Sitting: Don't slouch when sitting on a chair and don't sit with your legs crossed. Don't rest your chin in your hand. If you sit on a floor, sit upright by sitting on your folded legs (B) Standing: Rest your weight on your both feet evenly, and don't lean against a wall (C) Sleeping: Using a hard mattress or futon, lie on your back, keeping your neck straight with a low pillow or flattened towel (D) Eating: Bring the food to your mouth without tilting your head forward.

	Masticate looking straight ahead and not downward (E) Walking: Walk with long strides while swinging your arms (F) Others: Don't carry a heavy package with one hand. Don't thrust your head forward." Non-intervention control group were given generalised instructions emphasising painless jaw use during normal activity and restriction of some specific jaw activities such as extreme opening or chewing hard foods
Outcomes	Pain-free unassisted mouth opening (one decimal point by the examiner using slide callipers to measure right or left inter-incisal distance added to values of overbite), pain intensity (100mm VAS), disturbance in daily life.
Notes	

Risk of bias

Bias	**Authors judgement**	**Support for judgement**
Random sequence generation (selection bias)	High risk	Random allocation - details not described.
Allocation concealment (selection bias)	High risk	Not described.
Blinding (performance bias and detection bias) All outcomes	High risk	Not described.
Incomplete outcome data (attrition bias) All outcomes	High risk	No reasons given for drop-out. No intention-to-treat analysis conducted
Selective reporting (reporting bias)	High risk	Detail missing when presenting findings.
Other bias	High risk	Not enough detail about methods used in the paper.

Litt 2010

Methods	Randomised controlled trial conducted in: US Number of centres: 1 Recruitment period: October 2003 to July 2007 Funding source: NIDCR and NIH Trial identification number: Not stated	
Participants	52 were assigned to the standard treatment plus cognitive-behavioural skills training group, and 49 were assigned to the standard treatment. Inclusion: patients needed to have a positive Axis I diagnosis on the Research Diagnostic Criteria (RDC) for temporomandibular disorders (positive on at least one symptom-based group), and could have no contraindications to TMD treatment (as determined by the consulting oral surgeon). Exclusion criteria: lack of fluency in English (as determined by inability to read and understand a statement of informed consent); previous surgery for treatment of TMD pain; history of rheumatoid disease; extensive anatomical destruction or deterioration of the TM joint; diagnosed as having pain of neuropathic or odontogenic origin; carrying a diagnosis of psychosis; current use of antidepressants or anxiolytics; taking opioid pain medication; or pregnancy (due to possible adverse effects in pregnancy with the prescription of non-steroidal anti-inflammatory drugs).	
Intervention	Standard treatment (STD) condition entailing the placement of a flat-plane disoccluding splint, the prescription of non-steroidal anti-inflammatory drugs, and instruction for a soft diet Standard treatment plus CBT condition (STD + CBT) in which patients received all elements of STD, but also received cognitive-behavioural coping skills training. Each treatment was 6-weeks long	
Outcomes	Pain intensity (MPI), characteristic pain intensity, Depression: 20-item CES-D, activity Interference (MPI).	
Notes		
Risk of bias		
Bias	**Authors judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computerised urn randomisation procedure. The two arms were balanced on gender, age, ethnic background, pain level recorded at baseline, and RDC Axis I diagnoses
Allocation concealment (selection bias)	High risk	Participants informed of their treatment assignments.
Blinding (performance bias and detection bias) All outcomes	High risk	Pretreatment and follow-up assessments conducted by a research associate who was not blinded to the treatment condition

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Of 196 persons screened, 121 were deemed eligible for the study, and 101were assigned to treatment. At post-treatment 88%of patients provided data, and 73% provided data at 52 weeks. Losses to follow-up were equivalent across treatment conditions
Selective reporting (reporting bias)	Low risk	Relevant outcomes considered.
Other bias	Unclear risk	Power calculation included - quote: "This number of participants was sufficient to, at a minimum, detect significant between group differences at post-treatment on each of the major dependent variables, with a power of .8 and alpha set at .05."

Shedden-Mora 2013

Methods	Randomised controlled trial conducted in: Germany Number of centres: 1 Recruitment period: Not stated Funding source: Not stated Trial identification number: Not stated
Participants	29 were assigned to the biofeedback-based cognitive behavioural treatment and 29 were assigned to the dental treatment with occlusal splint. Inclusion: a painful axis I TMD diagnosis according to the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD), in other words group I (myofascial pain), or group III (arthralgia, arthritis, arthrosis) or both; patients could also have a group II diagnosis (disk displacement), but a painless group II diagnosis was not sufficient for study inclusion; pain present for at least 3 months; age between 18 and 70. Exclusion: presence of an OS already matching to our standards, for example an OS as described below (patients could be included if they currently used a splint that did not meet our standards, such as a non-OS); need for further diagnostic investigation or need for dental/maxillofacial treatment, as judged by a specialized dentist; other major chronic pain conditions predominant in disability, for example chronic low back pain or headache, as assessed in the diagnostic interview; major medical or psychiatric conditions that would interfere with the ability to participate.
Intervention	Aim of the study was to assess the efficiency of Bio feedback based cognitive-behavioural treatment (BFM-CBT) versus the occlusal splint therapy (OS). In addition changes in nocturnal masseter muscle activity (NMMA) was also investigated. Participants were randomly assigned to two groups 1) those who received eight weekly sessions of BFB-CBT 2) those who received OS treatment. Primary outcome measures were based on changes in pain intensity and disability. Secondary outcomes included emotional functioning, pain coping, somatoform symptoms, treatment satisfaction, and adverse events. NMMA was assessed during 3 nights pre-treatment and post treatment with portable devices. Follow up assessments was caries out 6 months after the treatment.
Outcomes	Characteristic pain intensity was calculated by averaging ratings of current pain, average pain, and worst pain in the past month on a numeric rating scale from 0 to 10, as recommended by RDC/TMD. Pain-related disability (PDI). Jaw use limitations (JDL) from the RDC/TMD. Depressive symptoms (CES-D). General anxiety symptoms (GAD-7). Cognitive and behavioral pain coping strategies (FESV). Somatoform complaints during the past week (SOMS-7.) TMD-related symptoms, such as jaw pain, toothache, or dizziness (a 41-item TMD symptom list). Participant ratings of global improvement (PGIC). Satisfaction with treatment (a 13-item rating scale adapted from a randomized controlled trial for chronic tinnitus).
Notes	
Risk of bias	

Bias	Authors judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Random assignment to conditions was generated by a researcher not involved in the study with the use of randomization software (GraphPad Software Inc., La Jolla, CA), and assignment was concealed in closed envelopes."
Allocation concealment (selection bias)	Unclear risk	Quote: "Random assignment to conditions was generated by a researcher not involved in the study with the use of randomization software (GraphPad Software Inc., La Jolla, CA), and assignment was concealed in closed envelopes."
Blinding (performance bias and detection bias) All outcomes	Low risk	Quote: "Assessor blinded."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "ITT used for dropouts."
Selective reporting (reporting bias)	Low risk	No evidence of selective reporting
Other bias	Unclear risk	Not stated

Townsend 2001

Methods	Randomised controlled trial conducted in: United states Number of centres: 1 Recruitment period: Not stated Funding source: Not stated Trial identification number: Not stated
Participants	10 were assigned to the treatment group and 10 were assigned to the wait-list control group. Inclusion: report of pain in temporomandibular joint or surrounding musculature in the past year; plus one of following: a) locked jaw, b) mandibular joint sounds, c) stiffness, tenderness or tightness in jaw, d) pain in ears, temple or cheek, e) uncomfortable bite; 18 to 55 years of age; access to email or telephone. Exclusion: head or facial surgery; diagnosis of degenerative joint disorder; currently taking psychotropic medication; pregnancy.
Intervention	Habit reversal treatment with minimal therapist contact (n = 10) versus waiting list control (n = 10). Both interventions lasted 20 weeks Habit reversal - 7-lesson manual appropriate for a self-help format: Lesson 1 included an overview and rationale for treatment including the role of stress and oral habits in facial pain. Individuals were introduced to the concept of identifying, detecting and recording oral habits and given specific exercises to practice doing so Lesson 2 included awareness training exercises, including deep breathing and a structured oral habits diary was introduced Lesson 3 involved learning to use facial exercises and deep breathing as competing responses for oral habits. The content of the oral habits diary was reviewed and elaborated on in order to detect life situations where oral habits are likely to occur In lesson 4 the exercises from previous lessons continued and progressive muscle relaxation exercises were introduced via written materials and audiotape. Exercises and examples of how to develop individually and situationally specific incompatible behaviours were provided and negative practice as an awareness training exercise was introduced In lesson 5 practice exercises for simulating the use of the various habit interruption and reversal exercises were introduced and the use of negative practice for nocturnal bruxing was reviewed Lesson 6 added a visualisation exercise and a shorter version of the relaxation training exercise to enhance participant's awareness of changing levels of muscle tension caused by oral habits In the final lesson participants reviewed the previous exercises, emphasising again the need to practice skills they had learned. An extensive discussion of relapse prevention and how to prevent relapses was also presented. Throughout the treatment participants reviewed difficulties applying techniques during the previous week. The use of positive self-statements and contingent rewards for implementing the exercises was emphasised. Each lesson included a review of the previous lesson, troubleshooting, goal setting, and record keeping components Waiting list controls - patients contacted therapist who advised them of waiting

	time	
Outcomes	Mean weekly pain rating (from pain diary), highest pain intensity rating for week (from pain diary), number of pain-free days (from pain diary), maladaptive oral habits (oral habits questionnaire), life interference (MPI), stress (Hassles scale)	
Notes	Highest pain intensity rating for week (from pain diary).	
Risk of bias		
Bias	**Authors judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Quote: "The two conditions (treatment and control) were assigned numeric values prior to participant recruitment and a random number table was consulted to determine the order of assignment. Participants were randomly assigned to condition via blocked randomization utilizing blocks of two."
Allocation concealment (selection bias)	High risk	Block randomisation. Following drop-out, next person allocated to space left
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Quote: "The therapist was naive to group assignment until after the treatment orientation, at which time the therapist referred to the random assignment list and assigned the participant to the next available position. The therapist then presented condition- specific information (e.g., when they would receive their first lesson or how long they could anticipate waiting for treatment to begin)."
Incomplete outcome data (attrition bias) All outcomes	High risk	No follow-up of drop-out data. Quote: "Missing data at post-treatment analysed using last observation carried forward (i.e. score at baseline)"
Selective reporting (reporting bias)	Unclear risk	Not enough detail.
Other bias	Unclear risk	Recruitment through advertisement in local paper.

Turk 1993

Methods	Randomised controlled trial conducted in: US Number of centres: 1 Recruitment period: Not stated Funding source: Not stated Trial identification number: Not stated
Participants	30 were assigned to the interocclusial appliance (IA) group, 30 were assigned to the biofeedback /stress management treatment group, and 20 were assigned to a 6-week awaiting list control group. Inclusion: pain and tenderness of the muscles of mastication and TMJ region; limited mandibular movements of at least 2 months; at least 18 years of age. Exclusion: no evidence of serious psychopathology (not operationalised); no history of TMJ related surgery.
Intervention	Interocclusial appliance (IA) (n = 30) versus biofeedback (BF) and stress management(SM) (n = 30) versus waiting list controls (n = 20). All interventions lasted 6 weeks IA - flat heat-cured acrylic resin splint constructed on the maxillary or mandibular arch. Patients instructed to wear at all times (except eating/dental hygiene). Weekly sessions included instruction in oral habits. Review and adjustment of IA BF/SM - biofeedback (compute controlled tone and pulsating feedback proportionate to masseter muscle tension levels) Stress management included: i) didactic education on link between stress, muscle tension and pain; ii) training in cognitive coping skills e.g. attention diversion; iii) homework in relaxation skills Waiting list controls - "Patients assigned to the WL group received the same pretreatment assessment procedures as the IA and BF/SM groups. At the time of the pretreatment evaluation, WL patients were informed that there was a waiting list for treatment and were scheduled for a second appointment 6 weeks later."
Outcomes	Pain (PSS from the MPI, PPI), depression (CES-D and POMS), credibility rating for patients in the active treatment groups (a set of five 10-point scales developed by Borkovec and Nau).
Notes	Comparison for this paper in the review was between the BF/SM group as intervention and IA group as control

Risk of bias

Bias	**Authors judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Not stated.
Allocation concealment (selection bias)	Unclear risk	Not enough information. Consecutive referrals were recruited. Random assignment to IA versus BF/SM versus waiting list control
Blinding (performance bias and	Unclear risk	Insufficient detail.

detection bias) All outcomes		
Incomplete outcome data (attrition bias) All outcomes	High risk	No detail provided of numbers of excluded individuals.
Selective reporting (reporting bias)	Unclear risk	Insufficient detail.
Other bias	Unclear risk	Insufficient detail.

Turk 1996

Methods	Randomised controlled trial conducted in: United States Number of centres: 1 Recruitment period: Not stated Funding source: National Institute Dental Research, National Institutes of Health Trial identification number: U.S. Public Health Service Research Grant R01 DE07514
Participants	24 were assigned to a combination of IA (i.e., a flat occlusal splint), SM plus SC (IA + SM + SC) and 24 were assigned to IA and SM plus CT for depression (IA + SM + CT). Inclusion: pain and tenderness of the muscles of mastication and TMJ region and restricted mandibular opening of 3-months duration or longer; no evidence of serious psychopathology; no history of TMJ-related surgeries; at least 18 years of age
Intervention	A combination of IA, SM plus SC (IA + SM + SC) (n = 22) versus IA + SM + CT (n = 23) IA = intraoral appliance; SM = stress management with biofeedback; SC = supportive counselling; CT = cognitive therapy. Therefore the comparison was between CT and SC IA + SM- "All patients received a standardized 6-week treatment program that combined an IA and SM, previously demonstrated to be effective in treating TMD (Turk 1993). The IA treatment component consisted of a full-arch, flat, acrylic resin splint and was constructed on the maxillary or mandibular arch. This treatment component was delivered by two prosthodontists trained in TMD treatment." The SM treatment component consisted of 6weekly sessions conducted by a psychologist trained in biofeedback-assisted relaxation procedures and stress management treatment of TMD patients. Biofeedback involved electrodes over the masseter muscle and computer- controlled auditory tone and pulsating feedback directly proportionate to masseter muscle tension levels. "In addition to biofeedback, the SM protocol also included (a)didactic education regarding the association between stress, increased muscle tension, and pain; (b) information and training in the use of cognitive coping skills (e.g. attention diversion) to control pain; (c) training in a progressive muscle relaxation exercise; and (d) homework assignments to help patients practice relaxation skills without the biofeedback instrumentation." CT group received standardised CT for depression. "This treatment focused on the identification of cognitive distortions or maladaptive thoughts regarding events that increased feelings of helplessness, hopelessness, and limited self-control. Strategies, individualized to the patient's unique circumstances were developed to help the patient eliminate or reduce these maladaptive cognitions, thereby reducing negative affect in response to life events." SC - this was delivered by a therapist whose role was "to provide unconditional and non directive support as the patient discussed general life stressors. Thus, time and attention from the therapist was consistent across treatment conditions, as was the opportunity to communicate in general about stressors. Although patients in this treatment protocol were given the opportunity to discuss stressors, cognitive distortions were not challenged, and they were not taught skills for reducing such maladaptive cognitions."

Outcomes	4 physical measures were used and included: (a) a muscle palpation pain index, an aggregate of the number of painful muscle sites, based on the bilateral examination of the 10 muscle sites recommended in the RDC; (b) a TMJ palpation pain index, an aggregate of the number of painful responses, based on the specific joint palpation sites recommended in the RDC for TMD; (c) unassisted mandibular opening without pain; and (d) maximum unassisted mandibular opening Other measures included: McGill pain questionnaire, BDI, pain catastrophising scale (CSQ), interference scale (MPI), oral-parafunctional habits scale, self-reported use of medication, self-reported use of health care resources for TMJ pain
Notes	Difficult to decipher components as there were many i.e. 3 interventions and then components of the 3 interventions

Risk of bias

Bias	**Authors judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Not mentioned.
Allocation concealment (selection bias)	Unclear risk	Not mentioned.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Not mentioned.
Incomplete outcome data (attrition bias) All outcomes	High risk	No intention-to-treat analysis reported.
Selective reporting (reporting bias)	Low risk	Nothing that suggests selective reporting.
Other bias	Unclear risk	Insufficient detail.

Turner 2006

Methods	Randomised controlled trial conducted in: United States Number of centres: 1 Recruitment period: 2001-2004 Funding source: NIDCR Trial identification number: Not stated	
Participants	79 were assigned to the cognitive-behavioural therapy and 79 were assigned to the education/attention control condition. Inclusion: age 18 years or older; an RDC/TMD Axis I TMD diagnosis made by an oral medicine specialist based on a structured RDC/TMD clinical examination; residence within a 2-hr drive of the TMD clinic; facial pain for at least 3 months; facial pain-related disability, as defined by a chronic pain grade of II high, III, or IV; ability to communicate in English. Exclusion: (assessed by the patient's oral medicine specialist and the study coordinator) needed for further diagnostic evaluation; pending litigation or disability compensation for pain; current or previous CBT for pain; and major medical or psychiatric conditions that would interfere with ability to participate.	
Interventions	CBT and education/attention - 4 sessions with 15mins phone calls between sessions and further calls 2,4,8,12,16,20 and 24 weeks after fourth session. Usual treatment - All study participants received treatment as usual from their dentist at the Orofacial Pain Clinic. These treatments were conservative and typically included instruction in jaw posture monitoring and correction (including instruction to keep jaws relaxed and teeth apart, but no training in muscle relaxation techniques), advice to apply heat and/or cold to painful facial areas, and recommendations concerning diet modifications. Medications (e.g., non-steroidal anti-inflammatory drugs), jaw stretching exercises, and occlusal splints were prescribed for some patients.	
Outcomes	Activity interference (GCPS, CPI), jaw use limitations (MFIQ), depression (BDI), process measures pain beliefs (SOPA, TMD SES), pain catastrophizing (CSQ, PCS), pain coping (CPCI), treatment credibility, TMD knowledge, treatment helpfulness	
Notes	Results displayed in the paper are shown as a total % effect explained by various mediators on: activity interference, pain intensity, masticatory scores, non-masticatory scores with CBT, as no significant effect was found for CBT versus attention and education	
Risk of bias		
Bias	**Authors judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Quote: "Randomization assignments were generated by a biostatistician (LM) using randomly selected block sizes of two or four using the sample function of the S-PLUS statistical software (Insightful Corporation,

		Seattle, WA) to prevent determination of the treatment assignment"
Allocation concealment (selection bias)	Low risk	Treatment assignments were recorded on slips of paper numbered consecutively within each stratum and sealed in envelopes sequentially numbered by stratum. Randomisation assignment was concealed to all study personnel until envelopes were opened by research staff after subject consent was obtained.
Blinding (performance bias and detection bias) All outcomes	Low risk	Outcome measures were self-reported so outcomes blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Followed up at telephone calls or next session.
Selective reporting (reporting bias)	Low risk	Insignificant results reported.
Other bias	Unclear risk	Insufficient detail.