Psychosocial interventions for the management of chronic orofacial pain (Review)

Aggarwal VR, Lovell K, Peters S, Javidi H, Joughin A, Goldthorpe J

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[Intervention Review]

Psychosocial interventions for the management of chronic orofacial pain

Vishal R Aggarwal[1], Karina Lovell[2], Sarah Peters[3], Hanieh Javidi[1], Amy Joughin[1], Joanna Goldthorpe[1]

[1]Oral Health Unit, School of Dentistry, The University of Manchester, Manchester, UK. [2]School of Nursing, Midwifery and Social Work, The University of Manchester, Manchester, UK. [3]School of Psychological Sciences, The University of Manchester, Manchester, UK

Contact address: Vishal R Aggarwal, Oral Health Unit, National Primary Care Research and Development Centre, School of Dentistry, The University of Manchester, Higher Cambridge Street, Manchester, M15 6FH, UK. vishal.r.aggarwal@manchester.ac.uk.

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ABSTRACT

Background

Psychosocial factors have a role in the onset of chronic orofacial pain. However, current management involves invasive therapies like occlusal adjustments and splints which lack an evidence base.

Objectives

To determine the efficacy of non-pharmacologic psychosocial interventions for chronic orofacial pain.

Search methods

The following electronic databases were searched: the Cochrane Oral Health Group Trials Register (to 25 October 2010), the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2010, Issue 4), MEDLINE via OVID (1950 to 25 October 2010), EMBASE via OVID (1980 to 25 October 2010) and PsycINFO via OVID (1950 to 25 October 2010). There were no restrictions regarding language or date of publication.

Selection criteria

Randomised controlled trials which included non-pharmacological psychosocial interventions for adults with chronic orofacial pain compared with any other form of treatment (e.g. usual care like intraoral splints, pharmacological treatment and/or physiotherapy).

Data collection and analysis

Data were independently extracted in duplicate. Trial authors were contacted for details of randomisation and loss to follow-up, and also to provide means and standard deviations for outcome measures where these were not available. Risk of bias was assessed and disagreements between review authors were discussed and another review author involved where necessary.

Main results

Seventeen trials were eligible for inclusion into the review. Psychosocial interventions improved long-term pain intensity (standardised mean difference (SMD) -0.34, 95% confidence interval (CI) -0.50 to -0.18) and depression (SMD -0.35, 95% CI -0.54 to -0.16). However, the risk of bias was high for almost all studies. A subgroup analysis revealed that cognitive behavioural therapy (CBT) either alone or in combination with biofeedback improved long-term pain intensity, activity interference and depression. However the studies pooled had high risk of bias and were few in number. The pooled trials were all related to temporomandibular disorder (TMD).

Authors' conclusions

There is weak evidence to support the use of psychosocial interventions for chronic orofacial pain. Although significant effects were observed for outcome measures where pooling was possible, the studies were few in number and had high risk of bias. However, given the non-invasive nature of such interventions they should be used in preference to other invasive and irreversible treatments which also have limited or no efficacy. Further high quality trials are needed to explore the effects of psychosocial interventions on chronic orofacial pain.

PLAIN LANGUAGE SUMMARY

Psychosocial interventions for the management of chronic orofacial pain

Studies indicate that psychological factors are associated with chronic pain in the face, mouth or jaws. However, current management, particularly in dentistry, does not target these factors. This review therefore explored whether behavioural interventions like cognitive behavioural therapy (CBT), biofeedback and posture regulation compared with usual care could improve outcomes for patients with chronic orofacial pain. We found that such interventions improved long-term pain intensity, pain interference with daily life activities and depression. However, the quality of the studies was poor and there were few studies from which we could combine results. We therefore recommend further high quality trials are needed to support the use of such interventions for chronic orofacial pain.

BACKGROUND

Description of the condition

There are four recognisable symptom complexes of chronic orofacial pain that may coexist: temporomandibular disorder (myofacial face pain); atypical facial pain (atypical facial neuralgia); atypical odontalgia (phantom tooth pain); and burning mouth (oral dysaesthesia, glossodynia, glossopyrosis). These chronic orofacial pain conditions have been considered as medically unexplained symptoms affecting the region of the mouth and face (Madland 2001; Wessely 1999), as pathological changes fail to explain the associated symptoms. Recent research has also shown that these conditions share common characteristics and cluster together into a single group based on these shared characteristics (Woda 2005). Epidemiological research has taken this evidence forward by 'lumping' these conditions together and collectively terming them as chronic orofacial pain, defined as pain in the face, mouth or jaws that has been present for a day or longer in the past month, and that has been present for 3 months or longer. The results of this research supports previous findings and showed that chronic orofacial pain thus defined had distinct characteristics based on pain descriptors, patterns and comorbidities that distinguished it from other commonly reported dental pains (Aggarwal 2008a). This work not only provides evidence that chronic orofacial pain encompasses a group of distinct conditions, but also shows that chronic orofacial pain co-occurs with other frequently unexplained syndromes like chronic widespread pain, irritable bowel syndrome and chronic fatigue, and that it shares common psychosocial factors with these syndromes (Aggarwal 2006), and may therefore be part of a wider spectrum of chronic pain disorders.

Description of the intervention

Psychosocial interventions targeted towards changing thoughts, behaviours and/or feelings that may exacerbate pain symptoms through a vicious cycle.

How the intervention might work

Psychosocial interventions may assume two possible models for chronic orofacial pain.

1. Inactivity - where persistent physical symptoms of pain lead to patients learning to avoid physical activity due to fear of exacerbating their condition. In turn, these negative cognitive and behavioural responses prolong and intensify symptoms (Gheldof 2006). The intervention would target this fear-avoidance behaviour to alleviate symptoms by a return to normal functioning. This mechanism considers central pain processing mechanisms.

2. Over activity - emotional stress (anxiety, depression, anger) may increase pain by precipitating activity in psychophysiological systems that are also activated by noxious events and provoke substantial autonomic, visceral and skeletal activity. The interactions among these biological systems are well illustrated by the 'anxiety-pain-tension' cycle that has been proposed to account for some forms of chronic pain (Wall 1999). This vicious cycle is frequently encountered in chronic orofacial pain conditions like temporomandibular pain dysfunction whereby psychosocial factors like life stress and anxiety provoke grinding of teeth and sustained contraction of muscles of the face. This produces pain which provokes further anxiety, which in turn produces prolonged muscle spasm at trigger points, as well as vasoconstriction, ischaemia and release of pain producing substances. This will then further reduce physical activity, and consequently muscle flexibility, muscle tone, strength and physical endurance. All the above lead to the commonly observed physical symptoms of temporomandibular pain dysfunction such as limited mouth opening and the feeling that teeth are not fitting properly. Fear avoidance and consequent disability due to disuse has been described in other chronic pain conditions (Gheldof 2006). Psychological factors also modulate pain responses and the limbic system that is responsible for emotional responses inhibits pain stimuli via descending pathways (Wall 1999). An alteration of this system as encountered in emotional disturbances (anxiety, depression, anger, etc) will lead to reduced inhibition via the descending pathways and thus an increase in pain (Wall 1999). Psychosocial interventions have the potential to target these negative thoughts, behaviours and/or feelings that may exacerbate pain symptoms and therefore should be a priority for investigation. The intervention would target the underlying stressor responsible for overactivity and induce a return to normal functioning. This mechanism is likely to work through changes in peripheral nociception.

Why it is important to do this review

Although patients with chronic orofacial pain do not have underlying organic abnormalities for reported symptoms, their management tends to be influenced by the background of the clinician assessing them and therefore tends to follow the current biomedical model which focuses on identifying underlying abnormal pathology for reported symptoms. Patients are therefore subjected to multiple tests and treatments in search for such a cause. Pfaffenrath 1993 showed that patients with atypical facial pain had consulted on average 7.5 (range 1 to 20) different doctors per patient: 91% dentists, 80% physicians, 66% neurologists, 63% ear, nose and throat surgeons, 31% each orthopaedics and maxillofacial surgeons, 23% psychiatrists, 14% neurosurgeons and 6% each ophthalmologists and dermatologists (n = 30). This resulted in a range of treatments varying from surgery (60%), antidepressant drugs (69%), analgesics (69%), and a range of physical therapies. No patients considered any form of surgery to be helpful and, in many, the pain was made worse. Recent research has also exposed this pattern of multiple consultations and lack of agreement in terminology and management of these patients (Aggarwal 2008a; Elrasheed 2004). This imposes a huge burden on already stretched healthcare resources.

Evidence from systematic reviews has also shown no beneficial effects of therapies such as irreversible occlusal adjustments (Koh 2003) and splints (Al-Ani 2004) that are targeted towards the correction of mechanical factors with which temporomandibular joint pain (one of the entities that constitute chronic orofacial pain) is thought to be associated. Epidemiological investigations have also shown that such mechanical factors thought to be associated with chronic orofacial pain represent heightened awareness of body symptoms generally and are not specific to chronic orofacial pain (Aggarwal 2008b).

There is also strong evidence to show that chronic orofacial pain is associated with psychological factors (Aggarwal 2006; Macfarlane 2001; Macfarlane 2002; Macfarlane 2004) and co-occurs with other medically unexplained symptoms (Aggarwal 2006). Further, there is growing evidence from randomised controlled trials (Gatchel 2006; Turner 2006) that early biopsychological interventions like cognitive behavioural therapy (CBT) and biofeedback mechanisms can improve outcome in patients with chronic orofacial pain conditions like temporomandibular pain. Given these strong psychological associations and lack of associations with mechanical factors, the use of extensive invasive therapy in the management of chronic orofacial pain does not appear to be justified. Early intervention with psychosocial therapies such as CBT should be a priority for investigation as it has the potential to target negative thoughts, behaviours and/or feelings that may exacerbate pain symptoms through a vicious cycle.

OBJECTIVES

To determine the efficacy of psychosocial interventions in the management of chronic orofacial pain.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs) which include psychosocial interventions for 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 (TMDs), atypical facial pain, atypical odontalgia, burning mouth syndrome. Other terms used to describe these conditions will also be 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, temporomandibular joint syndrome, stomatodynia.

Types of interventions

Psychosocial interventions targeted towards changing thoughts, behaviours and/or feelings that may exacerbate pain symptoms through a vicious cycle.

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.
2. Pain severity - impact (activity interference, function and/or distress) scores measured using validated scales (e.g. brief pain inventory, multidimensional pain inventory, hospital anxiety and depression scale).
3. Satisfaction with pain relief.
4. Quality of life.

Secondary outcomes

1. Service use - number of consultations to clinicians.

Compliance with the intervention was also to be recorded where reported.

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 strategy used a combination of controlled vocabulary and free text terms and was linked with the Cochrane Highly Sensitive Search Strategy (CHSSS) for identifying randomised 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 5.1.0 (updated March 2011) (Higgins 2011). Details of the MEDLINE search are provided in Appendix 1. The searches of EMBASE and PsycINFO were linked to the Cochrane Oral Health Group filters for identifying RCTs.

There were no restrictions regarding language.

Electronic searches

The following electronic databases were searched.

- Cochrane Oral Health Group's Trials Register (to 25 October 2010) (*see*Appendix 2).
- The Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library*, 2010, Issue 4) (*see*Appendix 3).
- MEDLINE via OVID (1950 to 25 October 2010) (*see*Appendix 1).
- EMBASE via OVID (1980 to 25 October 2010) (*see*Appendix 4).
- PsycINFO via OVID (1950 to 25 October 2010) (*see*Appendix 5).

Searching other resources

The reference lists of all eligible trials were checked for additional studies. Where these had not already been searched as part of the Cochrane Journal Handsearching Programme, the journals were handsearched by the review authors if electronic copies were not available. The search attempted to identify all relevant studies irrespective of language. Translated copies of non-English papers were obtained. The principal review author is a member of the International Association for Studies on Pain (IASP) Orofacial Pain Special Interest Group and contacted key members of this group to ascertain whether they knew of any unpublished material.

Data collection and analysis

Selection of studies

The title and abstracts of articles and reports resulting from the search strategy were screened independently and in duplicate by

two review authors. 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. Studies rejected at this or subsequent stages were recorded in the 'Characteristics of excluded studies' table along with reasons for exclusion.

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 and excluded studies are presented in their respective tables (*see* Characteristics of included studies and Characteristics of excluded studies). Any differences were resolved by discussion. Prior to data extraction the form was piloted using three studies and all review authors extracting the data participated in the piloting so that they were clear about the extraction process. The 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, as described above, and in accordance with the approach described in Chapter 8 of the Cochrane Handbook (Higgins 2011). This is a two-part tool addressing six specific domains as follows.

- Random sequence generation (selection bias).
- Allocation concealment (selection bias).
- Blinding of participants/caregivers (where feasible) and outcome assessors (performance bias and detection bias).
- Incomplete outcome data (attrition bias).
- Selective reporting (attrition bias).
- Other bias.

Each domain in the tool includes one or more specific entries in a 'Risk of bias' table. Within each entry, the first part of the tool describes what was reported to have happened in the study, in sufficient detail to support a judgement about the risk of bias. The second part of the tool assigns a judgement relating to the risk of bias for that entry. This is achieved by assigning a judgement of 'Low risk' of bias, 'High risk' of bias, or 'Unclear risk' of bias. After taking into account the additional information provided by the authors of the trials, studies were graded into the following categories.

- Low risk of bias: low risk of bias for all key domains.
- Unclear risk of bias: unclear risk of bias for one or more key domains.
- High risk of bias: high risk of bias for one or more key domains.

A risk of bias table was completed for each included study (*see* Characteristics of included studies). Results are presented graphically by study (Figure 1) and by domain over all studies (Figure 2).

Figure 1. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

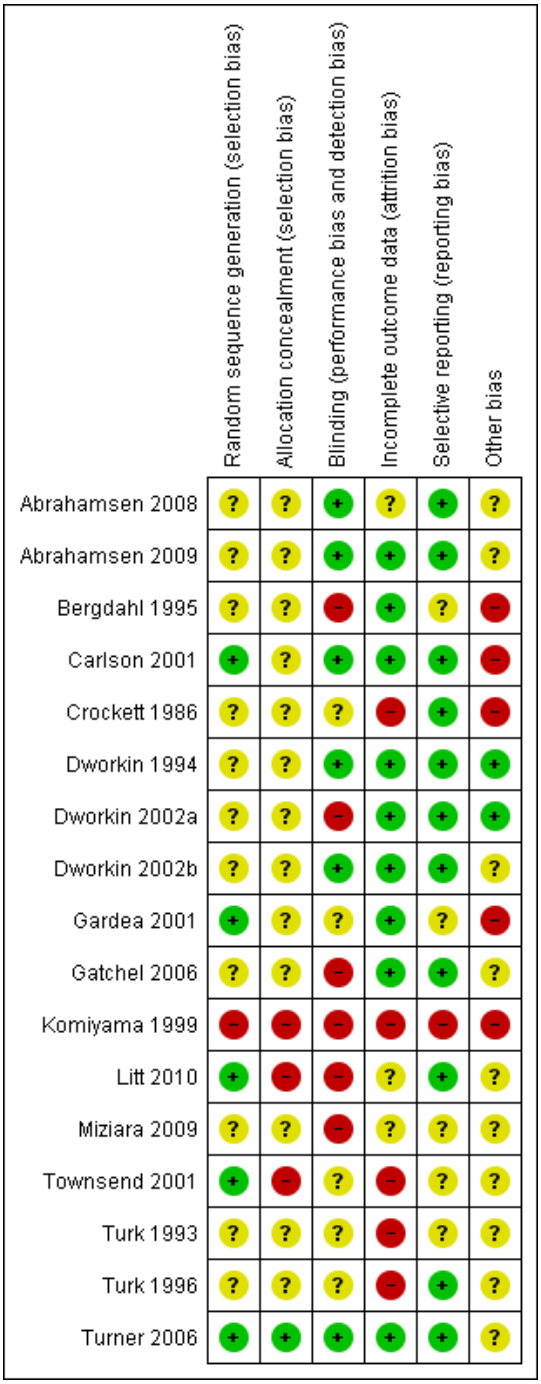
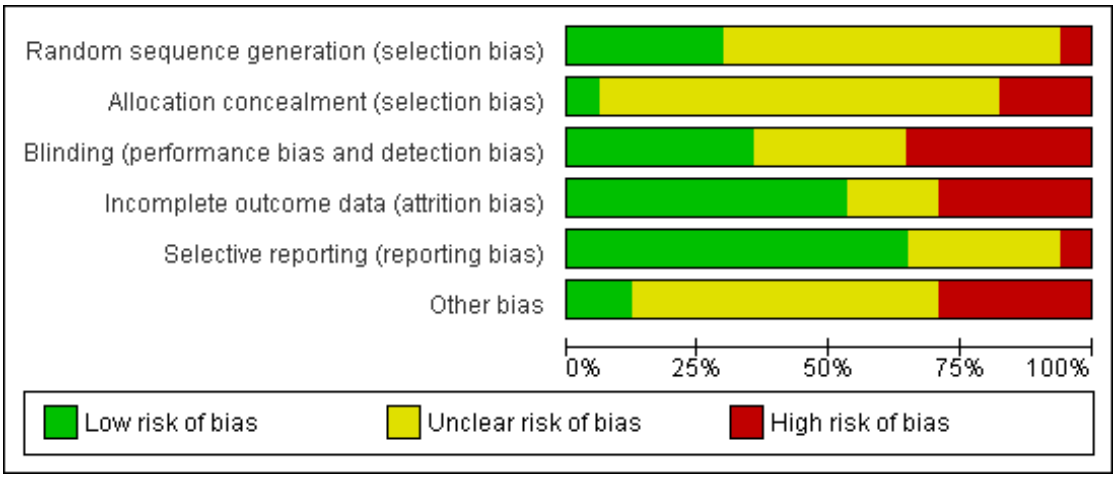


Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.



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 RevMan 5 software (RevMan 2011).

Dealing with missing data

Trial authors were contacted to retrieve missing data where necessary.

The analyses generally included only the available data (ignoring missing data), however methods for estimating missing standard deviations in Chapter 7.7.3 of the Cochrane Handbook (Higgins 2011) were to be used if required. No imputations or statistical methods to allow for missing data were used.

Assessment of heterogeneity

Clinical heterogeneity was assessed by examining the participants, interventions and outcome measures included in the trials. Statistical heterogeneity was assessed by means of Cochran's test for heterogeneity and quantified by the I^2 statistic.

Assessment of reporting biases

The strength and generalisability of the evidence was assessed by taking into account issues around publication bias and internal and external validity.

Data synthesis

Meta-analyses was only carried out if trials were of similar comparisons reporting the same outcome measures. Estimates of effect were combined using a random-effects model if three or more trials were available for analysis, otherwise the fixed-effect model was to be used. Risk ratios were combined for dichotomous outcomes, and mean differences for continuous outcomes or standardised mean differences where the same outcome was measured using different scales.

Subgroup analysis and investigation of heterogeneity

Subgroup analysis was intended on the type of chronic orofacial pain investigated. However, all studies included were based on TMD pain and this was therefore not possible.

Sensitivity analysis

We were unable to undertake this due to insufficient data. Data permitting, we would have used sensitivity analyses to examine the

effect of allocation concealment, intention-to-treat analysis and blind outcome assessment on the overall estimates of effect.

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies.

Detailed descriptions of the studies are in the 'Characteristics of included studies' and 'Characteristics of excluded studies' tables.

Results of the search

The initial search strategy yielded 525 references which were assessed blind and independently by two review authors, and based on the abstracts and titles these were reduced to 38 relevant manuscripts. Main reasons for exclusion were that a large proportion of studies were not trials and others were not on chronic orofacial pain.

All the 38 manuscripts identified were data extracted by the lead author. Data extraction was duplicated by sharing blind and independently between the other review authors. Twenty-three manuscripts were relevant for inclusion and represented 17 studies (six papers were follow-up studies of the same trial).

Included studies

Of the 17 included trials, 15 were on temporomandibular disorders (TMDs) and two trials investigated burning mouth syndrome. Twelve of the TMD trials included comparable control groups that had usual treatment which involved conservative treatment composed of education, counselling and an intraoral flat plane appliance. However, the trials on burning mouth syndrome used an attention placebo and placebo pills as controls (Bergdahl 1995; Miziara 2009) whilst the Townsend 2001 and Turk 1993 studies used waiting list controls. As Turk 1993 had an intraoral appliance comparison, this was used as a usual treatment comparison and this study included in the main comparison.

However, of the 12 studies eligible for pooling, Dworkin's two studies (Dworkin 2002a; Dworkin 2002b) and Komiyama's study (Komiyama 1999) displayed results graphically and we did not have means and standard deviations (SDs) to pool these studies. Trial authors were contacted to obtain data but only provided means with no SDs or did not respond. These three studies could therefore not be included in the meta-analysis. Overall, therefore, nine TMD trials were eligible for pooling. Even within these nine studies, there was much heterogeneity whereby studies did not use the same intervention, did not measure similar outcomes and some reported only short-term changes whilst others reported only long-term changes. Therefore, based on the information available from the included trials, psychological interventions were grouped into the following: cognitive behavioural therapy (CBT) alone, biofeedback alone, combination of CBT and biofeedback and physical self-regulation which was used by one trial (Carlson 2001). 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.

Excluded studies

From the 38 manuscripts identified for detailed extraction, 15 studies were excluded as they were not randomised controlled trials or had the wrong disease definition and/or patient group.

Risk of bias in included studies

Risk of bias plots are displayed in Figure 1 and Figure 2; the former showing the overall risk of bias and the latter individual plots for each study.

Allocation

This was reported by only one study (Turner 2006) and overall the risk of bias in this area was therefore high.

Blinding

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 poor with only four of the included studies (Carlson 2001; Dworkin 1994; Dworkin 2002b; Turner 2006) adequately reporting blinding for assessing outcome measures.

Incomplete outcome data

Only seven of the 17 trials included reported on missing outcome data and were assessed as being at low risk of bias for this domain.

Selective reporting

Nine of the 17 included trials were assessed as being at low risk of bias for selective reporting.

Other potential sources of bias

The studies were conducted in tertiary care settings which specialised in the management of chronic orofacial pain. This may affect the generalisability 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. The overall assessment of risk of bias shows two studies (Dworkin 1994; Turner 2006) to be at unclear risk of bias and the remaining 15 trials to be at high risk of bias (Figure 1).

Other weaknesses

The main criticism included lack of standardised outcome measures and comparable control groups which made it difficult to pool the results.

Effects of interventions

Psychosocial interventions versus usual care

Pain (short term)

Overall seven studies provided comparable data for this outcome but, because there was substantial heterogeneity (I^2 = 63%), the results could not be pooled. Looking at individual interventions, there was no statistically significant difference for CBT, biofeedback or posture self-control in comparison to usual care.

However, there was a statistically significant difference between combination therapy (CBT/biofeedback) and usual care, favouring the usual care (standardised mean difference (SMD) 0.46, 95% confidence interval (CI) 0.02 to 0.90). The results of these were due to the Turk 1993 study which showed greater improvement for the intraoral appliance group post-treatment. However, at 6-months follow-up the results were the same as the intervention group.

Two studies did not provide data in a suitable format for meta-analysis. The Komiyama 1999 paper did not show any differences at 12-month follow-up between the CBT intervention and control groups. In contrast, the comprehensive care programme study (Dworkin 2002b) showed significant improvement in short-term pain intensities between CBT and usual care.

Pain (long term)

Overall seven studies provided data on this outcome and there was a statistically significant difference in favour of psychosocial interventions (SMD -0.34, 95% CI -0.50 to -0.18), and this represented a 17% improvement in long-term pain for psychosocial interventions versus usual care. There was low heterogeneity (I^2 = 13%) which justified our decision to pool results for this outcome.

Looking at the individual interventions, there were statistically significant differences between the intervention group and usual care for CBT (SMD -0.25, 95% CI -0.46 to -0.05) and combination therapy (SMD -0.52, 95% CI -0.82 to -0.23) but not for biofeedback alone or posture self-control.

Two studies did not provide data in a suitable format for meta-analysis. The Dworkin self-care intervention (Dworkin 2002a) showed significant (P < 0.05) improvement in long term pain intensity whilst the comprehensive care programme study (Dworkin 2002b) did not.

Muscle palpation pain (long term)

Only three studies provided data on this outcome and because there was substantial heterogeneity (I^2 = 64%), the results could not be pooled. There was insufficient evidence to draw any conclusions regarding any of the individual interventions with regard to muscle palpation pain (long term).

One study did not provide data in a suitable format for meta-analysis but the self-care intervention showed significant (P < 0.05) improvement in this outcome (Dworkin 2002a).

Activity interference (long term)

Five studies provided data for this outcome but, because there was substantial heterogeneity (I^2 = 91%), the results could not be pooled.

Individually, there was a statistically significant difference between CBT and usual care (SMD -0.27, 95% CI -0.51 to -0.03) and there was insufficient evidence to draw conclusions for any other interventions with regard to activity interference.

Two studies did not provide data in a suitable format for meta-analysis. The Dworkin self-care intervention (Dworkin 2002a) showed significant (P < 0.05) improvement in this outcome whilst the comprehensive care programme study (Dworkin 2002b) did not.

Depression (long term)

Overall six studies provided data on this outcome and there were statistically significant differences in favour of psychosocial interventions (SMD -0.35, 95% CI -0.54 to -0.16) and this represented a 27% improvement in long-term pain for psychosocial interventions versus usual care. There was low heterogeneity (I^2 = 21%).

Individually, both CBT alone and CBT/biofeedback show statistically significant benefit over usual care with regard to depression (SMD -0.31, 95% CI -0.55 to -0.06) and (SMD -0.49, 95% CI -0.81 to -0.17) respectively.

CBT versus attention placebo

The Bergdahl 1995 study on burning mouth syndrome showed significant improvement (P < 0.001) in burning mouth intensity in the cognitive therapy group compared with attention placebo controls both at post-treatment (SMD -2.4, 95% CI -3.4 to -1.4) and 6-months follow-up (SMD -2.79, 95% CI -3.83 to -1.75). The data from the Miziara 2009 study on burning mouth syndrome versus placebo pill were not used as there were inconsistencies in reporting which were not clarified by the authors i.e. the risk ratio in the paper was 1.85 (95% CI 1.0 to 3.5; P = 0.04). However, the raw data presented in the paper was used, the risk ratio was calculated as 1.77 (95% CI 0.98 to 3.21; P = 0.06).

Habit reversal versus waiting list control

The Townsend 2001 study showed that habit reversal significantly improved mean pain ratings post-treatment compared to waiting list controls (SMD -1.31, 95% CI -1.97 to -0.65). Due to the nature of the control groups the study could not make comparisons at follow-up (the controls had to start treatment within 20 weeks of being enrolled in the trial) although pain improvement was maintained in the treatment group at 8-month follow-up (mean = 0.76; SD = 0.68). Similarly, habit reversal showed improvement in life interference postoperatively (SMD -0.86, 95% CI -1.79 to 0.06) and at 8-month follow-up (mean = 20.96; SD = 13.79). However, due to insufficient information we cannot draw conclusions with regard to habit reversal versus waiting list control (one trial at high risk of bias) or cognitive therapy versus attention placebo (one trial at high risk of bias).

Hypnosis versus relaxation

Both studies on hypnosis used similar methodologies and were conducted by the same group. Unfortunately these only measured short-term outcomes and, although they showed a reduction in pain intensity, depression and anxiety, the pooled results were only significant for depression (SMD -0.49, 95% CI -0.93 to -0.04) and pain intensity (SMD -1.84, 95% CI -3.26 to -0.42). More high quality studies that measure long-term outcomes are needed to explore the efficacy of hypnosis in the management of chronic orofacial pain.

DISCUSSION

Summary of main results

This systematic review has shown that there is only weak evidence to support the use of behavioural psychosocial interventions to improve long-term outcomes for patients with chronic orofacial pain. Although there were significant effects for improvement of long-term pain and depression, the studies were at high risk of bias and there were small numbers of studies that could be pooled. The subgroup analysis of individual interventions revealed that the strength of evidence was greatest for cognitive behavioural therapy (CBT) which, either alone or in combination with biofeedback, resulted in long-term improvement in activity interference, pain and depression. Again, however, the studies had high risk of bias and where pooling was possible this included a maximum of three studies.

Overall completeness and applicability of evidence

The meta-analysis could only be performed on trials for temporomandibular pain dysfunction and therefore the strength of evidence for other chronic orofacial pain conditions is questionable as there was only one study relating to burning mouth syndrome, and this could not be pooled into the meta-analysis due to incomparable control groups.

Furthermore, the interventions had a high degree of clinical heterogeneity. Although we grouped them together based on their behavioural components, the number of sessions, mode of delivery and the person delivering the intervention varied considerably from study to study. Nevertheless, a subgroup analysis showed that, amongst these interventions, the strongest evidence pertained to the use of CBT, although even for this the studies had high risk of bias and where pooling was possible this included a maximum of three studies.

Quality of the evidence

The risk of bias pertaining to each item discussed in the results section was moderate to high and the sample sizes for the studies were very small. This did not allow the studies to examine the mechanisms by which psychosocial interventions were improving outcomes. As discussed previously the CBT trials had the best quality of evidence compared to the other interventions. However, the evidence was still weak due to insufficient studies and high risk of bias amongst the majority. The Turner 2006 study, which had the lowest risk of bias, had adequate sample sizes and examined potential mediators, moderators and predictors of patient improvement with CBT. It was a novel study to examine whether pre- to post-treatment process variable changes mediated CBT effects on subsequent outcomes. 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 temporomandibular pain dysfunction. A further study (Litt 2010) also showed that somatization, self-efficacy and readiness for treatment were significant moderators. More high quality

studies along these lines are needed to strengthen the evidence for the use of behavioural interventions for chronic orofacial pain.

Potential biases in the review process

Heterogeneity of the clinical conditions included in defining of chronic orofacial pain

Although conditions encompassing chronic orofacial pain have been shown to cluster together (Woda 2005), the mechanisms remain unclear. However, the trials pooled together in this review were all based on temporomandibular pain dysfunction and therefore heterogeneity arising from the definition is unlikely to have affected the results although as discussed there was substantial heterogeneity when pooling for short-term pain intensity, muscle palpation pain and activity interference. More important was our decision to group together the behavioural interventions and this is likely to introduce substantial clinical heterogeneity. However, we looked at individual interventions in the subgroups and, although this limited the power, it showed that CBT significantly improved outcomes compared to the other interventions.

Agreements and disagreements with other studies or reviews

The current findings have extrapolated the results of our initial narrative review which assessed the use of CBT for chronic orofacial pain (Aggarwal 2010). This concluded that there was evidence to support the use of CBT in chronic orofacial pain. However, because it was a narrative review we did not quantify the effects in a meta-analysis. The current systematic review shows that, whilst there is evidence to favour the use of CBT, this evidence is weak as the studies had high risk of bias and where pooling was possible this included a maximum of three trials.

AUTHORS' CONCLUSIONS

Implications for practice

The results of this review provide some evidence, albeit weak, for the use of non-invasive psychosocial interventions in the management of chronic orofacial pain. Of the psychosocial interventions considered, the most promising evidence was for cognitive behavioural therapy (CBT) either alone or in combination with biofeedback. The use of invasive and irreversible techniques (e.g. some splints and occlusal adjustment) has been shown to have little or no effect in previous Cochrane reviews (Al-Ani 2004; Koh 2003) and are perceived to cause iatrogenic harm. Given that the CBT is non-invasive and unlikely to have side effects, its use in early management of chronic orofacial pain should be considered. However, further high quality trials are needed to strengthen the effects observed in our review as the evidence emerging was weak because the studies had high risk of bias, and where pooling was possible this included only a small number of trials. In addition, trials also need to encompass other chronic orofacial pain conditions apart from temporomandibular disorders (TMDs) and use a standardised protocol that outlines mode of delivery, number of sessions and who delivers the intervention.

Implications for research

We found weak evidence to favour the use of psychosocial interventions, in particular CBT, for chronic orofacial pain. Much still remains unanswered. There was no consensus on the number of sessions, mode of delivery and who should deliver the intervention. Furthermore, the mechanisms by which psychosocial interventions improve outcome remain unclear. Although the Turner 2006 and Litt 2010 studies explored mediators for CBT, much still remains unclear about how individual components of CBT interact and mediate the outcomes. Future research needs to use larger, high-quality studies to explore mechanisms by which CBT improves outcomes for chronic orofacial pain. Notwithstanding the limitations of the evidence, it would appear that CBT, as expected, influences pain coping as it had effects on long-term outcomes of pain intensity, activity interference and depression, and not on short-term pain intensities. Future studies also need to be conducted in primary care to explore whether early intervention can improve outcome. This certainly appears to be the case for early intervention in tertiary care (Gatchel 2006).

Future trials need to standardise outcome measures so that they can be comparable. Outcome domains for chronic pain clinical trials have been clearly researched and defined in a recent study and these would appear to be an appropriate standard for future trials to emulate (Turk 2008). In addition, future research needs to account for the theoretical bias arising from therapeutic alliance related to the quality of doctor-patient relationship which can drive non-specific effects (placebo effect in clinical practice, Hawthorne effect in clinical studies). CBT and biofeedback have been constructed according to a psychological model which permits such an evaluation and needs to be assessed in future studies in the orofacial pain field.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Abrahamsen 2008

Methods	Randomised controlled trial conducted in: Denmark Number of centres: 1 Recruitment period: Not stated Funding source: ViFAB, Danish Ministry of the Interior and Health and FUT-Calcin Foundation, Danish Dental Association Trial identification number: Not stated
Participants	41 participants. Inclusion criteria: "Persistent Idiopathic Orofacial Pain (PIOP) for more than 6 months with no pathological findings in clinical and radiological examinations in accordance with the following. (1) Facial pain present daily for at least 1 month and persisting for all or most of the day. (2) The pain was deep and poorly localised, of moderate or severe intensity, but not unbearable. (3) The pain is confined at onset to a limited area on one side of the head. (4) The pain is without paroxysms, precipitation from trigger areas, autonomic symptoms, sensory loss, and other physical signs; but dysaesthesia may occur. The pain was expressed as atypical facial pain, atypical odontalgia, stomatodynia, or in combination with TMD pains."
Interventions	Hypnosis (n = 22) versus relaxation controls (n = 19). Both 5 sessions Hypnosis - "consisted of progressive relaxation, guided imaginary instructions of a nice safe place, pain suggestions of controlling or changing the pain perception tailored individually and dissociation from the pain. During the trance state, it was attempted to improve the patient's individual coping with minor psychological problems and their stress-management skills in daily life according to their needs. Individual CDs with the patient's preferred pain suggestions were made and used to practice hypnosis at home." The paper gives further details of the intervention in an appendix Relaxation - trance "relaxation and visualizing a nice safe place, however, no further suggestions were given during trance."
Outcomes	Pain intensity (self-reported diary on a 0 to 10 VAS), Danish version of McGill pain questionnaire for pain character, perceived pain area using drawings, medication use, Pittsburgh sleep quality index (0 to 6), psychological symptoms measured using Danish version of symptom check list (SCL) which measured somatization, obsessive compulsive disorder, interpersonal sensitivity, depression, anxiety, hostility, and phobic anxiety, QOL - A Danish version of SF36, hypnotic susceptibility - A Danish version of Stanford Hypnotic Clinical Scale (SHCS), pain coping - Danish version of the Coping Strategies Questionnaire
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement

Abrahamsen 2008 (*Continued*)

Random sequence generation (selection bias)	Unclear risk	Not stated.
Allocation concealment (selection bias)	Unclear risk	Not stated.
Blinding (performance bias and detection bias) All outcomes	Low risk	Quote: "The subjects were blinded to the treatment and had no previous experience with hypnosis. The subjects were informed that two types of hypnotic treatment were tested; one with an audio-CD with which they could practice hypnosis at home and another without the CD. The subjects in the control group believed that they received hypnotic intervention. The clinician was blinded to the hypnotisability during treatment. All data were entered by a blinded assistant."
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	3 drop-outs from control group were omitted from study.
Selective reporting (reporting bias)	Low risk	No evidence of selective reporting as a range of outcomes measured and reported
Other bias	Unclear risk	There were baseline differences between intervention and control groups in social functioning. Also although pain diaries showed significant differences in intensity between intervention and outcome, this finding was not replicated in the present pain intensity scores of the McGill pain questionnaire where the differences were not significant

Abrahamsen 2009

Methods	Randomised controlled trial conducted in: Denmark Number of centres: 1 Recruitment period: Not stated Funding source: ViFAB, Danish Ministry of the Interior and Health and FUT-Calcin Foundation, Danish Dental Association Trial identification number: Not stated
Participants	40 participants. Inclusion criteria: myofascial TMD pain according to the Research Diagnostic Criteria (RDC TMD), type 1ab, and in addition type IIIab were allowed. The inclusion criteria for the daily pain intensity pain was > 3 on a Numerical Rating scale (NRS) with a duration of 6 months or longer

	At inclusion previous experience with hypnosis was not acceptable but experience with relaxation was allowed
Interventions	Hypnosis (n = 20) versus relaxation (n = 20). Hypnosis - "hypnotic intervention consisted of a standardized hypnotic induction procedure followed by progressive relaxation, guided imaginary instructions of an autobiographic comfortable place according to their individual preference (e.g. beach, garden and forest). Perceptions of colours, sounds, smells and kinaesthetic sensations were integrated into the suggestions. Furthermore, suggestions of feelings of success, calm, peace of mind and inner strengths were given and connected to the image of being in a comfortable place. Suggestions of controlling or changing the pain perception were tailored individually according to the preferences of the patients together with suggestions to dissociate from the pain. In addition, hypnotic suggestions were given with the aim of improving the patients' stress management skills as well as their coping with minor psychological problems. Every patient in the hypnosis group received a compact disc with hypnotic suggestions with instructions to practice hypnosis at home." Relaxation - "No hypnotic pain suggestions were given. Patients in this group received a compact disc with relaxation instructions to be used at home. Progressive muscle relaxation throughout the body from the head with particular emphasis on orofacial muscles, progressive relaxation of neck, shoulder, arms, back, chest, stomach, pelvis and legs. Guided imaginary to an autobiographic nice, safe place according to individual preference (beach, garden and forest)."
Outcomes	Pain intensity (self-reported diary on a 0 to 10 VAS), Danish version of McGill pain questionnaire for pain character, perceived pain area using drawings, medication use, Pittsburgh sleep quality index (0 to 6), psychological symptoms measured using Danish version of symptom check list (SCL) which measured somatization, obsessive compulsive disorder, interpersonal sensitivity, depression, anxiety, hostility, and phobic anxiety, QOL - A Danish version of SF36, hypnotic susceptibility - A Danish version of Stanford Hypnotic Clinical Scale (SHCS), pain coping - Danish version of the Coping Strategies Questionnaire
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote: "The patients were randomly assigned by drawing lots"
Allocation concealment (selection bias)	Unclear risk	Not stated.
Blinding (performance bias and detection bias) All outcomes	Low risk	Quote: "The patients were enrolled in the study consecutively and informed that two types of hypnotic treatment were tested, and both the patients in the hypnosis and the control group were informed that they received hypnotic intervention. The clini-

		cian, a dentist with special training in hypnosis for pain control, performed the hypnosis and was blinded to the hypnotic susceptibility of the patients during treatment. There was no reliability check of the intervention. All data were entered by an assistant who was blinded to the treatment condition."
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 as all outcomes considered
Other bias	Unclear risk	As per the 2008 trial on PIOP (Abrahamsen 2008), although pain diaries showed significant differences in intensity between intervention and outcome, this finding was not replicated in the present pain intensity scores of the McGill pain questionnaire where the differences were not significant There were also significant differences in some base-line characteristics (use of the pain coping strategy of self-statements. The hypnosis group had higher scores than control group. There was a difference between groups regarding OCDs. The control group had higher scores than the hypnosis group

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 participants with resistant burning mouth syndrome after odontological and medical treatment were included
Interventions	Cognitive therapy (CT) versus attention placebo (AO). 15 participants in each group 12 to 15 sessions lasting for 1 hour once a week. CT delivered by psychologists while AO by therapists. Components of AO and CT not described
Outcomes	Intensity of burning mouth measures on a non-validated VAS ranging from 1 to 7 (endurable to unendurable). Outcomes measured post-treatment and at 6 months
Notes	Components of intervention unclear.

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	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	44 participants - 23 in the intervention and 21 in the control group All participants were either active-duty or retired military personnel (Navy, Marine, Air Force, or Army) or family members of active-duty or retired military members. To be included in the study, 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
Interventions	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	Primary outcome was pain relief measured on VAS (0 to 100). Secondary outcomes included 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). Outcomes measured at 6 weeks and 26 weeks
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random assignment was accomplished by the use of a table of random numbers
Allocation concealment (selection bias)	Unclear risk	Not mentioned.

Carlson 2001 (*Continued*)

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	28 participants assigned to 3 intervention groups (7 in each group). 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
Interventions	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 30 min rest

Crockett 1986 (*Continued*)

	period
Outcomes	Interincisal opening (dentists rating), pain to palpation (dentists rating), global rating of worst pain during 3-weeks post-treatment (self-reporting), mean weekly frequency of pain (self-reporting), mean weekly intensity of pain (self-reporting), 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 (selection bias)	Unclear risk	Insufficient detail.
Allocation concealment (selection bias)	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	Partcipants 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 criteria included 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

Dworkin 1994 (*Continued*)

	the study
Interventions	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 detection bias) All outcomes	Low risk	Outcome measurement blinded - quote: "All clinical and self-report data were gathered at baseline and at 3- and 12-month follow-up by 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.

Dworkin 1994 (*Continued*)

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	Inclusion: "(1) 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; (2) RDC/TMD Axis II GCP score of 0, I or II-Low (3) age 18 to 70 years." Exclusion: "(1) pain attributable to confirmed migraine or head pain condition other than tension headache; (2) 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; and (3) necessity for emergency TMD treatment."
Interventions	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 extraoral 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**

Dworkin 2002a (*Continued*)

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	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 participants
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	Inclusion: "(1) 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; (2) RDC/TMD Axis II GCP score of II-High, III or IV (3) age 18 to 70 years." Exclusion: "(1) pain attributable to confirmed migraine or head pain condition other than tension headache; (2) acute infection or other significant disease of the teeth, ears, eyes, nose, or throat; (3) debilitating physical or mental illness; (4) necessity for emergency TMD treatment; (5) inability to speak or write English."
Interventions	Comprehensive care (CC) (n = 59) versus usual treatment (UT) (n = 58) CC - CBT-based programme for chronic pain adapted for TMD and included: behavioral/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 of motion, number of extraoral muscle palpations, SCL-90 depression, SCL-90 somatization, helpfulness and satisfaction

Dworkin 2002b (*Continued*)

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

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	108 participants aged 18 to 65 diagnosed with TMD using RDC criteria, TMD for at least 6 months Exclusion criteria eliminated individuals with a significant physical condition such as cancer, low-back pain and fibromyalgia, people with 6 or more DSM-IV Axis I diagnoses, a diagnosis of psychosis or active suicidal ideation, and those who did not meet the RDC criteria
Interventions	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. Standardised protocol developed by one of the authors who specialised in biofeedback and stress management techniques. The equip-

	ment 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 conceptualisations, 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
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.

Gardea 2001 (*Continued*)

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	101 adults aged 18 to 70 years who had acute jaw or facial pain that had been present for less than 6 months and who had been referred by dentists and oral surgeons to a TMD clinical research programme. Myofascial pain diagnosis was based on Axis I-Group 1a of the RDC examination form, which consisted of palpation of 20 muscle sites involved in the diagnosis of myofascial pain and the subjects responses to question number 3 from the RDC history questionnaire (Have you had pain in the face, jaw, temple, in front of the ear, or in the ear in the last month?). An oral surgeon who was knowledgeable in the RDC (EE) trained and periodically recalibrated the clinical personnel Patients were excluded as potential 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.
Interventions	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 scale)
Notes	

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 stated.
Blinding (performance bias and detection bias) All outcomes	High risk	Only one assessor used to measure outcomes due to scheduling problems and not clear whether blinded
Incomplete outcome data (attrition bias) All outcomes	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)."
Selective reporting (reporting bias)	Low risk	Relevant outcomes considered.

Gatchel 2006 (*Continued*)

Other bias	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

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	183 participants. Inclusion criteria: 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. 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."
Interventions	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, pain intensity (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	101 patients including 85 women and 16 men seeking treatment for a complaint of either bilateral or unilateral pain in the area of the temporomandibular joint that had persisted and was noticeable on a daily basis for a period of at least 3 months Recruited from dental medicine clinics (10%), from other dental referrers (< 5%), and from the community via newspaper and web-based advertisements offering free short-term treatment. None were referred from specialised facial pain clinics Inclusion criteria: "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)." "The mean age of the sample was 39.4 years (SD = 12.1). The majority of participants were white (79%), with 9% black, 9% of Hispanic origin, and 3% self-described as other. Forty-one percent were married or cohabiting. The average years of education was 14.7 (SD = 2.5). The participants reported having chronic TMD pain for 6.7 years on average (SD = 6.6), with a mean pain intensity rating of 3.5 on a scale to 6 (SD = 1.3)."
Interventions	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 versus a standard treatment plus CBT condition (STD + CBT) in which patients received all elements of STD, but also received cognitive-behavioral coping skills training. Each treatment was 6-weeks long
Outcomes	Pain intensity: multidimensional pain inventory (MPI); characteristic pain intensity Depression: 20-item Center for Epidemiological Studies Depression scale (CES-D) Activity Interference: interference scale from the 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

Litt 2010 (*Continued*)

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 101 were 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."

Miziara 2009

Methods	Randomised controlled trial conducted in: Brazil Number of centres: 1 Recruitment period: May 2002 to May 2007 Funding source: Not stated Trial identification number: Not stated
Participants	44 participants. Inclusion criteria: 1. Patients with BMS, without any other symptoms of systemic disease, e.g. primary BMS 2. Patients followed up at least for 3 months. 3. Patients who have signed an informed consent form and have accepted to undergo a psychotherapy group session if necessary Exclusion criteria: 1. Patients with a doubtful diagnosis. 2. Patients followed up for less than 3 months. 3. Patients who did not agree with the treatment.
Interventions	Group psychotherapy versus placebo pill. Group psychotherapy - 12 sessions once a week for 3 months. Difficult to decipher components as none described

Outcomes	Present pain intensity (Likert scale) and short form McGill pain questionnaire for pain character
Notes	No means or standard deviations provided.

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 stated.
Blinding (performance bias and detection bias) All outcomes	High risk	Not possible.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not stated.
Selective reporting (reporting bias)	Unclear risk	Nothing that suggests selective reporting although only pain intensity outcomes measured
Other bias	Unclear risk	Ethical issues may arise regarding use of placebo pill. No long-term outcomes assessment conducted

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	Inclusion criteria: 1. Report of pain in temporomandibular joint or surrounding musculature in the past year 2. 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 3. 18 to 55 years of age. 4. Access to email or telephone . Exclusion criteria: 1. Head or facial surgery. 2. Diagnosis of degenerative joint disorder. 3. Currently taking psychotropic medication.

	4. Pregnancy.
Interventions	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), MPI (life interference sub scale), 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

Townsend 2001 (*Continued*)

		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	80 participants. Inclusion criteria: 1. Pain and tenderness of the muscles of mastication and TMJ region 2. Limited mandibular movements of at least 2 months. 3. At least 18 years of age . Exclusion criteria: 1. No evidence of serious psychopathology (not operationalised) 2. No history of TMJ related surgery.
Interventions	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	CES-D (depression), profile of mood states (depression), PSS (pain severity subscale from Multidimensional Pain Inventory), PPI (muscle palpation pain index; sum of numbers of painful sites)
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 detection bias) All outcomes	Unclear risk	Insufficient detail.
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	Inclusion criteria: (a) pain and tenderness of the muscles of mastication and TMJ region and restricted mandibular opening of 3-months duration or longer, (b) no evidence of serious psychopathology, (c) no history of TMJ-related surgeries, and (d) at least 18 years of age
Interventions	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 6 weekly 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 nondirective 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, Beck depression inventory, pain

Turk 1996 (*Continued*)

	catastrophising scale from the coping strategies questionnaire (CSQ), interference scale from the multidimensional pain inventory, 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	156 participants. Inclusion criteria: 1. Age 18 years or older. 2. An RDC/TMD Axis I TMD diagnosis made by an oral medicine specialist based on a structured RDC/TMD clinical examination 3. Residence within a 2-hr drive of the TMD clinic. 4. Facial pain for at least 3 months. 5. Facial pain-related disability, as defined by a chronic pain grade of II high, III, or IV 6. Ability to communicate in English. Exclusion criteria: "Study exclusion criteria (assessed by the patient's oral medicine specialist and the study coordinator) were 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"

Turner 2006 (*Continued*)

Interventions	CBT and education/attention; usual treatment as a control.
Outcomes	Activity interference (primary outcome) GCPS, CPI, jaw use limitations (MFIQ), depression - BDI, process measures pain beliefs (SOPA, TMD SES), pain catastrophising (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.

VAS = visual analogue scale; TMD = temporomandibular disorder; OCD = obsessive compulsive disorder; SCL = symptom checklist; CBT = cognitive behavioural therapy; RDC = research diagnostic criteria; BMS = burning mouth syndrome; TMJ = temporomandibular joint

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Carlson 1991	No measure of pain in outcome.
Crider 2005	Not a randomised controlled trial.
De Laat 2003	Not a randomised controlled trial.
Erlandson 1989	Subjects age not 18 and over and half the patients had no pain at the start of the trial
Femiano 2004	Not a randomised controlled trial.
Flor 1993	Disease definition includes those with joint abnormalities and underlying pathology i.e. a number of patients had abnormal joint x-rays which implies this group does not have chronic non-specific orofacial pain
Funch 1984	Bias is high and outcome poorly assessed. Different outcome measures for short and long-term therapy and therefore not comparable. Relies on 2 single time points and the nature of pain is episodic so reliability cannot be assessed and subject to bias as done over telephone and does not state whether outcome assessors were blinded or not. Moreover it is difficult to compare the interventions without a control group
Jerjes 2007	Not a randomised controlled trial.
Michelotti 2004	Subjects age not 18 and over.
Oakley 1994	Not a randomised controlled trial.
Olson 1987	Not a randomised/controlled clinical trial (no control group and comparison group sought after randomisation into treatment groups had been done)
Stam 1984	Subjects age not 18 and over.
Stenn 1979	Subjects age not 18 and over, not a randomised controlled trial
Wahlund 2003	Subjects age not 18 and over.
Winocur 2002	Not a randomised controlled trial.

DATA AND ANALYSES

Comparison 1. Any psychosocial intervention versus usual care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pain short term (3 months or less)	7		Std. Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.1 CBT alone	4	411	Std. Mean Difference (IV, Fixed, 95% CI)	0.03 [-0.17, 0.22]
1.2 Biofeedback alone	2	45	Std. Mean Difference (IV, Fixed, 95% CI)	-0.41 [-1.06, 0.25]
1.3 Combination	2	90	Std. Mean Difference (IV, Fixed, 95% CI)	0.46 [0.02, 0.90]
1.4 Posture self-control	1	44	Std. Mean Difference (IV, Fixed, 95% CI)	-0.49 [-1.09, 0.11]
2 Pain long term (greater than 3 months)	7	658	Std. Mean Difference (IV, Fixed, 95% CI)	-0.34 [-0.50, -0.18]
2.1 CBT alone	4	383	Std. Mean Difference (IV, Fixed, 95% CI)	-0.25 [-0.46, -0.05]
2.2 Biofeedback alone	1	35	Std. Mean Difference (IV, Fixed, 95% CI)	-0.09 [-0.88, 0.70]
2.3 Combination	3	196	Std. Mean Difference (IV, Fixed, 95% CI)	-0.52 [-0.82, -0.23]
2.4 Posture self-control	1	44	Std. Mean Difference (IV, Fixed, 95% CI)	-0.52 [-1.13, 0.08]
3 Muscle palpation pain long term (greater than 3 months)	3		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
3.1 CBT alone	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
3.2 Combination	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
3.3 Posture self-control	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
4 Activity interference / disability long term (greater than 3 months)	5		Std. Mean Difference (IV, Fixed, 95% CI)	Subtotals only
4.1 CBT alone	4	285	Std. Mean Difference (IV, Fixed, 95% CI)	-0.27 [-0.51, -0.03]
4.2 Biofeedback alone	1	34	Std. Mean Difference (IV, Fixed, 95% CI)	-0.12 [-0.95, 0.71]
4.3 Combination	1	36	Std. Mean Difference (IV, Fixed, 95% CI)	-0.11 [-0.94, 0.72]
4.4 Posture self-control	1	44	Std. Mean Difference (IV, Fixed, 95% CI)	-2.95 [-3.82, -2.07]
5 Depression long term (greater than 3 months)	6	455	Std. Mean Difference (IV, Fixed, 95% CI)	-0.35 [-0.54, -0.16]
5.1 CBT alone	3	252	Std. Mean Difference (IV, Fixed, 95% CI)	-0.31 [-0.55, -0.06]
5.2 Combination	2	159	Std. Mean Difference (IV, Fixed, 95% CI)	-0.49 [-0.81, -0.17]
5.3 Posture self-control	1	44	Std. Mean Difference (IV, Fixed, 95% CI)	-0.12 [-0.71, 0.48]

Comparison 2. Habit reversal versus waiting list control

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pain short term (less than 3 months)	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
2 Life interference	1		Std. Mean Difference (IV, Fixed, 95% CI)	Totals not selected

Comparison 3. Cognitive therapy versus attention placebo

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pain short term (3 months or less)	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
2 Pain long term (greater than 3 months)	1		Std. Mean Difference (IV, Fixed, 95% CI)	Totals not selected

Comparison 4. Hypnosis versus relaxation

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pain short term	2	81	Mean Difference (IV, Fixed, 95% CI)	-1.84 [-3.26, -0.42]
2 Depression short term	2	81	Std. Mean Difference (IV, Fixed, 95% CI)	-0.49 [-0.93, -0.04]
3 Anxiety short term	2	81	Std. Mean Difference (IV, Fixed, 95% CI)	-0.42 [-0.86, 0.02]

Analysis 1.1. Comparison 1 Any psychosocial intervention versus usual care, Outcome 1 Pain short term (3 months or less).

Review: Psychosocial interventions for the management of chronic orofacial pain

Comparison: 1 Any psychosocial intervention versus usual care

Outcome: 1 Pain short term (3 months or less)

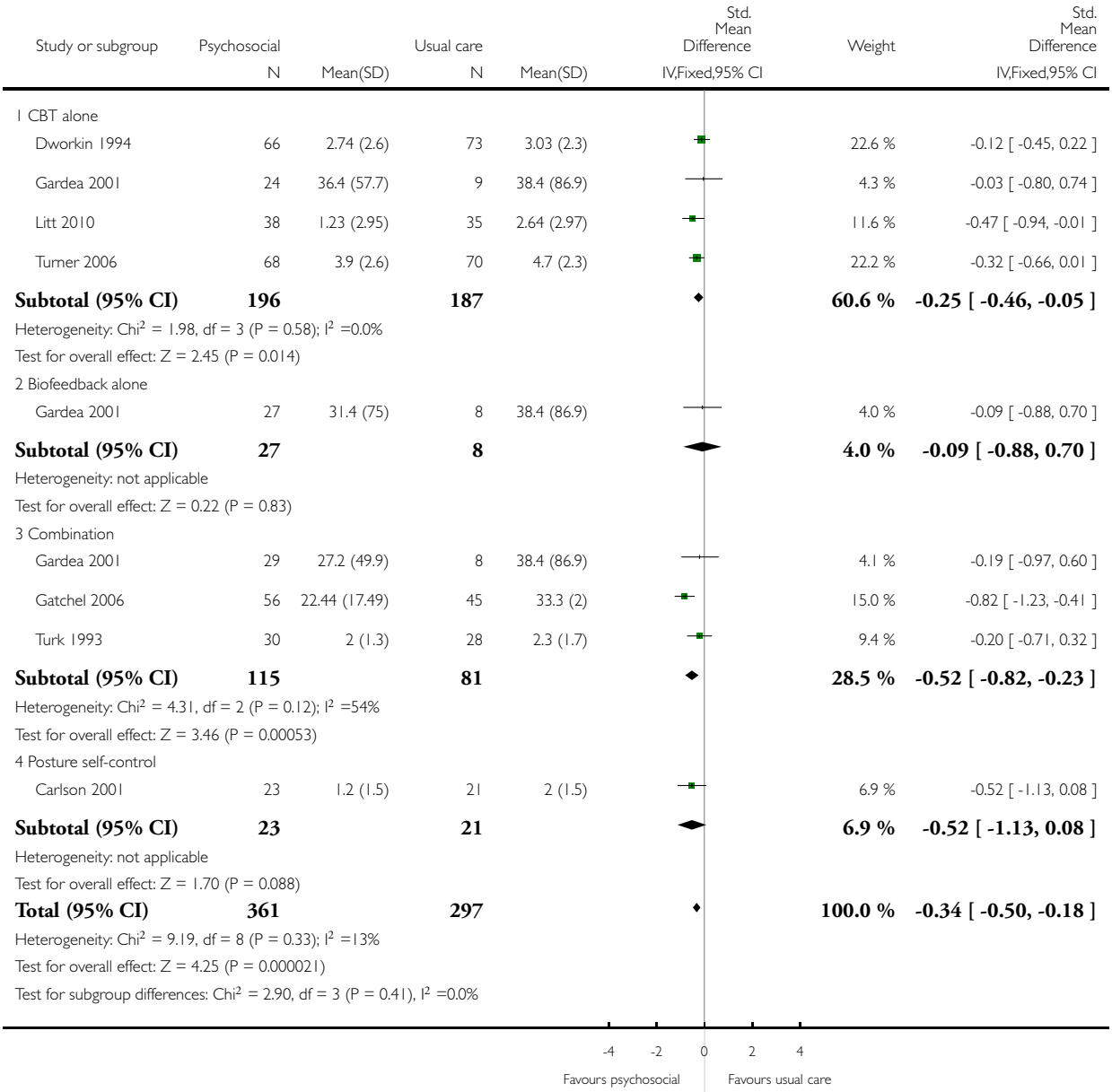
Study or subgroup	Psychosocial N	Mean(SD)	Usual care N	Mean(SD)	Std. Mean Difference IV,Fixed,95% CI	Weight	Std. Mean Difference IV,Fixed,95% CI
1 CBT alone							
Dworkin 1994	66	3.73 (2.5)	73	3.14 (2.4)		34.1 %	0.24 [-0.09, 0.57]
Gardea 2001	22	41.51 (16.83)	9	42.53 (23.56)		6.3 %	-0.05 [-0.83, 0.72]
Litt 2010	52	1.59 (2.3)	49	2.04 (2.07)		24.9 %	-0.20 [-0.60, 0.19]
Turner 2006	68	5.2 (1.9)	72	5.2 (2.1)		34.7 %	0.0 [-0.33, 0.33]
Subtotal (95% CI)	**208**		**203**			**100.0 %**	**0.03 [-0.17, 0.22]**
Heterogeneity: Chi² = 2.96, df = 3 (P = 0.40); I² =0.0%							
Test for overall effect: Z = 0.28 (P = 0.78)							
2 Biofeedback alone							
Crockett 1986	7	1.86 (1.06)	7	2.9 (0.89)		33.5 %	-0.99 [-2.13, 0.14]
Gardea 2001	23	40 (22.25)	8	42.53 (23.56)		66.5 %	-0.11 [-0.91, 0.70]
Subtotal (95% CI)	**30**		**15**			**100.0 %**	**-0.41 [-1.06, 0.25]**
Heterogeneity: Chi² = 1.56, df = 1 (P = 0.21); I² =36%							
Test for overall effect: Z = 1.21 (P = 0.23)							
3 Combination							
Gardea 2001	24	42.5 (15.11)	8	42.53 (23.56)		30.5 %	0.00 [-0.80, 0.80]
Turk 1993	30	2.4 (1.2)	28	1.6 (1.2)		69.5 %	0.66 [0.13, 1.19]
Subtotal (95% CI)	**54**		**36**			**100.0 %**	**0.46 [0.02, 0.90]**
Heterogeneity: Chi² = 1.81, df = 1 (P = 0.18); I² =45%							
Test for overall effect: Z = 2.03 (P = 0.043)							
4 Posture self-control							
Carlson 2001	23	1.6 (1.3)	21	2.4 (1.9)		100.0 %	-0.49 [-1.09, 0.11]
Subtotal (95% CI)	**23**		**21**			**100.0 %**	**-0.49 [-1.09, 0.11]**
Heterogeneity: not applicable							
Test for overall effect: Z = 1.59 (P = 0.11)							
Test for subgroup differences: Chi² = 8.11, df = 3 (P = 0.04), I² =63%							

Analysis 1.2. Comparison 1 Any psychosocial intervention versus usual care, Outcome 2 Pain long term (greater than 3 months).

Review: Psychosocial interventions for the management of chronic orofacial pain

Comparison: 1 Any psychosocial intervention versus usual care

Outcome: 2 Pain long term (greater than 3 months)



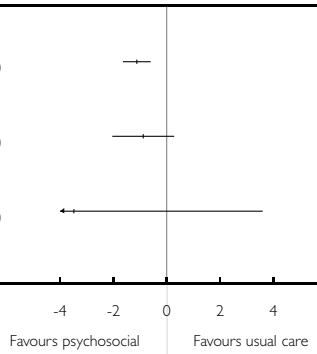
Analysis 1.3. Comparison 1 Any psychosocial intervention versus usual care, Outcome 3 Muscle palpation pain long term (greater than 3 months).

Review: Psychosocial interventions for the management of chronic orofacial pain

Comparison: 1 Any psychosocial intervention versus usual care

Outcome: 3 Muscle palpation pain long term (greater than 3 months)

Study or subgroup	Psychosocial N	Mean(SD)	Usual care N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 CBT alone						
Turk 1996	21	-3.82 (0.98)	20	-2.71 (0.71)		-1.11 [-1.63, -0.59]
2 Combination						
Turk 1993	30	1.8 (2.4)	28	2.7 (2.1)		-0.90 [-2.06, 0.26]
3 Posture self-control						
Carlson 2001	23	9.3 (10.5)	21	12.8 (13.2)		-3.50 [-10.59, 3.59]

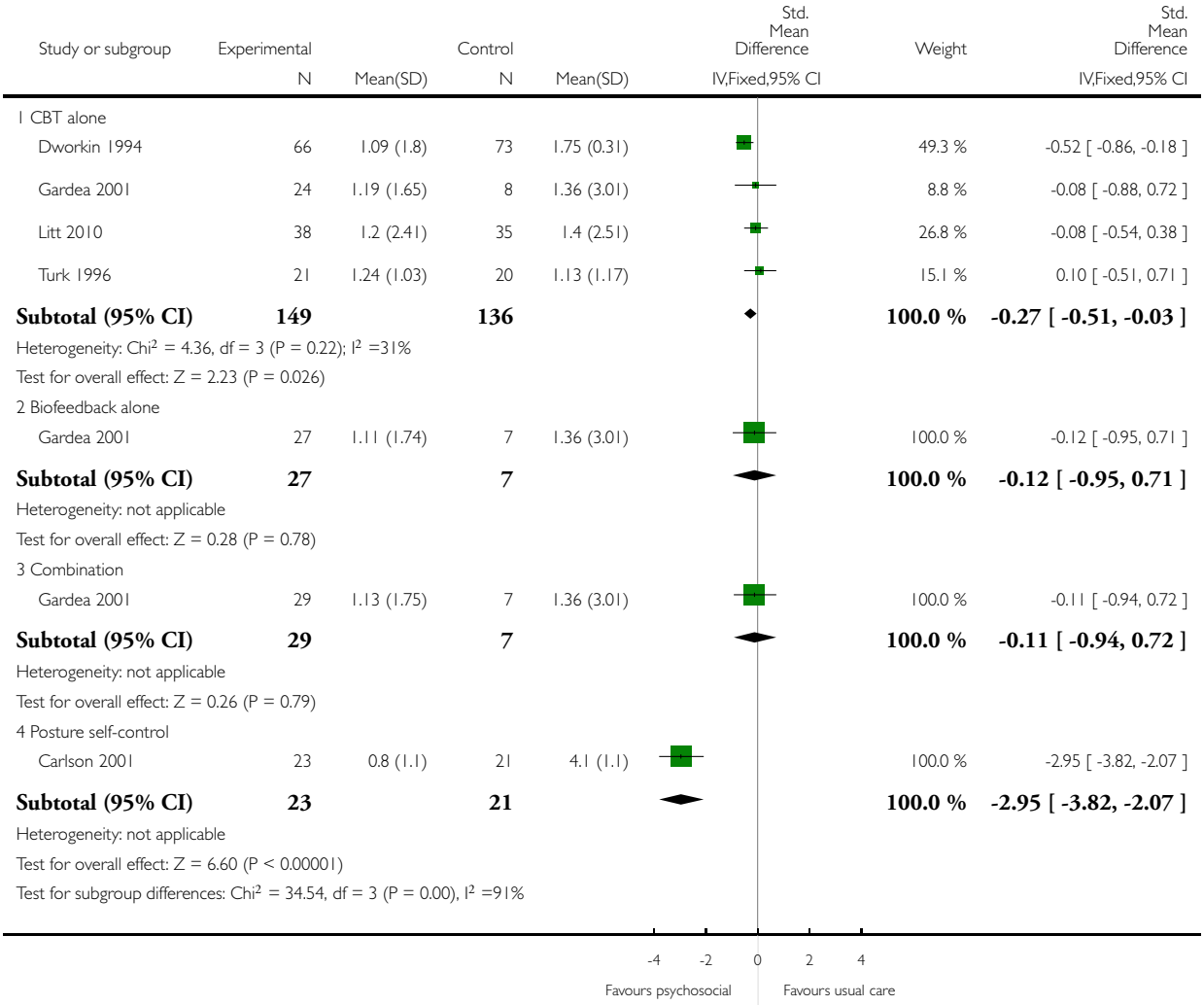


Analysis 1.4. Comparison 1 Any psychosocial intervention versus usual care, Outcome 4 Activity interference / disability long term (greater than 3 months).

Review: Psychosocial interventions for the management of chronic orofacial pain

Comparison: 1 Any psychosocial intervention versus usual care

Outcome: 4 Activity interference / disability long term (greater than 3 months)



Analysis 1.5. Comparison 1 Any psychosocial intervention versus usual care, Outcome 5 Depression long term (greater than 3 months).

Review: Psychosocial interventions for the management of chronic orofacial pain

Comparison: 1 Any psychosocial intervention versus usual care

Outcome: 5 Depression long term (greater than 3 months)

Study or subgroup	Experimental N	Mean(SD)	Control N	Mean(SD)	Std. Mean Difference IV,Fixed,95% CI	Weight	Std. Mean Difference IV,Fixed,95% CI
1 CBT alone							
Litt 2010	38	8.8 (23.11)	35	9.7 (21.1)		16.5 %	-0.04 [-0.50, 0.42]
Turk 1996	21	4.29 (3.47)	20	7.3 (4.27)		8.6 %	-0.76 [-1.40, -0.12]
Turner 2006	68	8.3 (9.1)	70	11.4 (10.1)		30.8 %	-0.32 [-0.66, 0.02]
Subtotal (95% CI)	**127**		**125**			**55.8 %**	**-0.31 [-0.55, -0.06]**
Heterogeneity: Chi^2 = 3.26, df = 2 (P = 0.20); I^2 =39%							
Test for overall effect: Z = 2.40 (P = 0.016)							
2 Combination							
Gatchel 2006	56	5.27 (6.98)	45	7.98 (9)		22.2 %	-0.34 [-0.73, 0.06]
Turk 1993	30	6.7 (5.8)	28	13.2 (10.4)		12.1 %	-0.77 [-1.30, -0.23]
Subtotal (95% CI)	**86**		**73**			**34.3 %**	**-0.49 [-0.81, -0.17]**
Heterogeneity: Chi^2 = 1.61, df = 1 (P = 0.20); I^2 =38%							
Test for overall effect: Z = 3.02 (P = 0.0025)							
3 Posture self-control							
Carlson 2001	23	0.3 (0.41)	21	0.35 (0.43)		9.9 %	-0.12 [-0.71, 0.48]
Subtotal (95% CI)	**23**		**21**			**9.9 %**	**-0.12 [-0.71, 0.48]**
Heterogeneity: not applicable							
Test for overall effect: Z = 0.39 (P = 0.70)							
Total (95% CI)	**236**		**219**			**100.0 %**	**-0.35 [-0.54, -0.16]**
Heterogeneity: Chi^2 = 6.33, df = 5 (P = 0.28); I^2 =21%							
Test for overall effect: Z = 3.69 (P = 0.00023)							
Test for subgroup differences: Chi^2 = 1.47, df = 2 (P = 0.48), I^2 =0.0%							

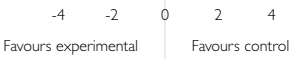
Analysis 2.1. Comparison 2 Habit reversal versus waiting list control, Outcome 1 Pain short term (less than 3 months).

Review: Psychosocial interventions for the management of chronic orofacial pain

Comparison: 2 Habit reversal versus waiting list control

Outcome: 1 Pain short term (less than 3 months)

Study or subgroup	Experimental N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
Townsend 2001	10	0.96 (0.57)	10	2.27 (0.89)		-1.31 [-1.97, -0.65]



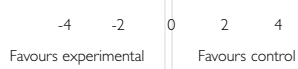
Analysis 2.2. Comparison 2 Habit reversal versus waiting list control, Outcome 2 Life interference.

Review: Psychosocial interventions for the management of chronic orofacial pain

Comparison: 2 Habit reversal versus waiting list control

Outcome: 2 Life interference

Study or subgroup	Experimental N	Mean(SD)	Control N	Mean(SD)	Std. Mean Difference IV,Fixed,95% CI	Std. Mean Difference IV,Fixed,95% CI
Townsend 2001	10	20.33 (11.46)	10	33.33 (16.84)		-0.86 [-1.79, 0.06]



Analysis 3.1. Comparison 3 Cognitive therapy versus attention placebo, Outcome 1 Pain short term (3 months or less).

Review: Psychosocial interventions for the management of chronic orofacial pain

Comparison: 3 Cognitive therapy versus attention placebo

Outcome: 1 Pain short term (3 months or less)

Study or subgroup	Experimental		Control		Mean Difference	Mean Difference
	N	Mean(SD)	N	Mean(SD)	IV,Fixed,95% CI	IV,Fixed,95% CI
Bergdahl 1995	15	2.2 (1)	15	4.6 (1.7)		-2.40 [-3.40, -1.40]

Analysis 3.2. Comparison 3 Cognitive therapy versus attention placebo, Outcome 2 Pain long term (greater than 3 months).

Review: Psychosocial interventions for the management of chronic orofacial pain

Comparison: 3 Cognitive therapy versus attention placebo

Outcome: 2 Pain long term (greater than 3 months)

Study or subgroup	Experimental		Control		Std. Mean Difference	Std. Mean Difference
	N	Mean(SD)	N	Mean(SD)	IV,Fixed,95% CI	IV,Fixed,95% CI
Bergdahl 1995	15	1.4 (1.1)	15	4.7 (1.2)		-2.79 [-3.83, -1.75]

Analysis 4.1. Comparison 4 Hypnosis versus relaxation, Outcome 1 Pain short term.

Review: Psychosocial interventions for the management of chronic orofacial pain

Comparison: 4 Hypnosis versus relaxation

Outcome: 1 Pain short term

Study or subgroup	hypnosis N	Mean(SD)	relaxation N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Abrahamsen 2008	22	3.9 (2.6)	19	5.8 (2.2)		93.4 %	-1.90 [-3.37, -0.43]
Abrahamsen 2009	20	2.9 (10.7)	20	3.9 (6.7)		6.6 %	-1.00 [-6.53, 4.53]
Total (95% CI)	**42**		**39**			**100.0 %**	**-1.84 [-3.26, -0.42]**

Heterogeneity: $Chi^2 = 0.09$, df = 1 (P = 0.76); $I^2 = 0.0\%$

Test for overall effect: Z = 2.54 (P = 0.011)

Test for subgroup differences: Not applicable

Analysis 4.2. Comparison 4 Hypnosis versus relaxation, Outcome 2 Depression short term.

Review: Psychosocial interventions for the management of chronic orofacial pain

Comparison: 4 Hypnosis versus relaxation

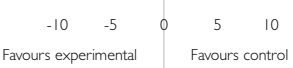
Outcome: 2 Depression short term

Study or subgroup	hypnosis N	Mean(SD)	relaxation N	Mean(SD)	Std. Mean Difference IV,Fixed,95% CI	Weight	Std. Mean Difference IV,Fixed,95% CI
Abrahamsen 2008	22	0.7 (0.5)	19	1 (0.9)		51.0 %	-0.41 [-1.03, 0.21]
Abrahamsen 2009	20	0.7 (0.4)	20	1.1 (0.9)		49.0 %	-0.56 [-1.20, 0.07]
Total (95% CI)	**42**		**39**			**100.0 %**	**-0.49 [-0.93, -0.04]**

Heterogeneity: $Chi^2 = 0.11$, df = 1 (P = 0.74); $I^2 = 0.0\%$

Test for overall effect: Z = 2.15 (P = 0.032)

Test for subgroup differences: Not applicable



Analysis 4.3. Comparison 4 Hypnosis versus relaxation, Outcome 3 Anxiety short term.

Review: Psychosocial interventions for the management of chronic orofacial pain

Comparison: 4 Hypnosis versus relaxation

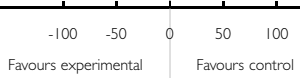
Outcome: 3 Anxiety short term

Study or subgroup	hypnosis		relaxation		Std. Mean Difference	Weight	Std. Mean Difference
	N	Mean(SD)	N	Mean(SD)	IV,Fixed,95% CI		IV,Fixed,95% CI
Abrahamsen 2008	22	0.5 (0.5)	19	0.8 (0.9)		50.5 %	-0.41 [-1.03, 0.21]
Abrahamsen 2009	20	0.5 (0.4)	20	0.8 (0.9)		49.5 %	-0.42 [-1.05, 0.21]
Total (95% CI)	**42**		**39**			**100.0 %**	**-0.42 [-0.86, 0.02]**

Heterogeneity: Chi^2 = 0.00, df = 1 (P = 0.98); I^2 =0.0%

Test for overall effect: Z = 1.85 (P = 0.064)

Test for subgroup differences: Not applicable



APPENDICES

Appendix 1. MEDLINE (OVID) search strategy

1. BURNING MOUTH SYNDROME/
2. ((burning adj3 mouth$) or (burning adj3 tongue$)).mp. GLOSSALGIA/
3. (glossalgia$ or glossdynia$ or glossopyros$ or stomatodyn$ or stomatopyros$).mp.
4. ("oral dysaesthesia" or "oral dysesthesia").mp.
5. exp CRANIOMANDIBULAR DISORDERS/
6. ("temporomandibular$" or "temporo-mandibular").mp.
7. tmj.mp. or tmd.ti,ab.
8. exp MYOFASCIAL PAIN SYNDROMES/
9. (myofascial and (pain$ or disorder$ or dysfunction$)).mp.
10. (myofacial and (pain$ or disorder$ or dysfunction$)).mp.
11. (atypical and odontol$).mp.
12. (atypical and toothache$).mp.
13. (atypical and "tooth pain").mp.
14. "phantom tooth pain".mp.
15. exp Facial Pain/
16. (atypical and "facial pain").mp.
17. (atypical and "facial neuralgia").mp.
18. or/1-18
19. exp BEHAVIOR THERAPY/
20. PSYCHOTHERAPY/

21. AUTOGENIC TRAINING/
22. exp COUNSELING/
23. SOCIAL SUPPORT/
24. ("behaviour therap$" or "behavior therap$").mp.
25. counsel$.mp.
26. "autogenic train$".mp.
27. (psychotherap$ or psychoanal$).mp.
28. ("self-help group" or "self help group" or communicat$ or educat$ or inform$).mp.
29. or/20-29
30. 19 and 30

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. drug therapy.fs.
6. randomly.ab.
7. trial.ab.
8. groups.ab.
9. or/1-8
10. exp animals/ not humans.sh.
11. 9 not 10

Appendix 2. The Cochrane Oral Health Group Register Search Strategy

(("burning mouth*" or "burning tongue*" or glossalgia* or glossdynia* or glossopyros* or stomatodyn* or stomatopyros* or "oral dysaethesia" or "oral dysesthesia" or 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 "behavior therap*" or counsel* or "autogenic train*" or psychotherap* or psychoanal* or self-help or "self help" or communicat* or inform* or educat*))

Appendix 3. Cochrane Central Register of Controlled Clinical Trials (CENTRAL) Search Strategy

#1 MeSH descriptor Burning Mouth Syndrome this term only
#2 ((burning in All Text near/3 mouth* in All Text) or (burning in All Text near/3 tongue* in All Text))
#3 MeSH descriptor Glossalgia this term only
#4 (glossalgia* in All Text or glossdynia* in All Text or glossopyros* in All Text or stomatodyn* in All Text or stomatopyros* in All Text)
#5 ("oral dysaesthesia" in All Text or "oral dysesthesia" in All Text)
#6 MeSH descriptor Craniomandibular Disorders explode all trees
#7 (temporomandibular* in All Text or temporo-mandibular* in All Text)
#8 (tmj in Title, Abstract or Keywords or tmd in Title, Abstract or Keywords)
#9 MeSH descriptor MYOFASCIAL PAIN SYNDROMES explode all trees
#10 (myofascial in All Text and (pain* in All Text or disorder* in All Text or dysfunction* in All Text))
#11 (myofacial in All Text and (pain* in All Text or disorder* in All Text or dysfunction* in All Text))
#12 (atypical in All Text and odontol* in All Text)
#13 (atypical in All Text and toothache* in All Text)
#14 (atypical in All Text and "tooth pain" in All Text)
#15 "phantom tooth pain" in All Text
#16 MeSH descriptor Facial Pain explode all trees

#17 (atypical in All Text and “facial pain” in All Text)
#18 (atypical in All Text and “facial neuralgia” in All Text)
#19 (#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 or #15 or #16 or #17 or #18)
#20 MeSH descriptor BEHAVIOR THERAPY explode all trees
#21 MeSH descriptor Psychotherapy this term only
#22 MeSH descriptor AUTOGENIC TRAINING this term only
#23 MeSH descriptor Counseling explode all trees
#24 MeSH descriptor Social Support this term only
#25 (“behaviour therap*” in All Text or “behavior therap*” in All Text)
#26 counsel* in All Text
#27 “autogenic train*” in All Text
#28 (psychotherap* in All Text or psychoanal* in All Text)
#29 (“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)
#30 (#20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29)
#31 (#19 and #30)

Appendix 4. EMBASE (OVID) Search Strategy

1. BURNING MOUTH SYNDROME/
2. ((burning adj3 mouth$) or (burning adj3 tongue$)).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
3. GLOSSALGIA/
4. (glossalgia$ or glossdynia$ or glossopyros$ or stomatodyn$ or stomatopyros$).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
5. (“oral dysaesthesia” or “oral dysesthesia”).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
6. exp CRANIOMANDIBULAR DISORDERS/
7. (“temporomandibular$” or “temporo-mandibular”).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
8. tmj.mp. or tmd.ti,ab. [mp=title, original title, abstract, name of substance word, subject heading word]
9. exp MYOFASCIAL PAIN SYNDROMES/
10. (myofascial and (pain$ or disorder$ or dysfunction$)).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
11. (myofacial and (pain$ or disorder$ or dysfunction$)).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
12. (atypical and odontol$).mp.
13. (atypical and toothache$).mp.
14. (atypical and “tooth pain”).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
15. “phantom tooth pain”.mp.
16. exp Facial Pain/
17. (atypical and “facial pain”).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
18. (atypical and “facial neuralgia”).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
19. or/1-18
20. exp BEHAVIOR THERAPY/
21. PSYCHOTHERAPY/
22. AUTOGENIC TRAINING/
23. exp COUNSELING/
24. SOCIAL SUPPORT/
25. (“behaviour therap$” or “behavior therap$”).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
26. counsel$.mp.
27. “autogenic train$”.mp.

28. (psychotherap$ or psychoanal$).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
29. ("self-help group" or "self help group" or communicat$ or educat$ or inform$).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
30. or/20-29
31. 19 and 30

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

Appendix 5. PsycINFO (OVID) Search Strategy

1. exp Myofascial pain/
2. ((burning adj3 mouth$) or (burning adj3 tongue$)).mp. [mp=title, abstract, heading word, table of contents, key concepts]
3. (glossalgia$ or glossdynia$ or glossopyros$ or stomatodyn$ or stomatopyros$).mp. [mp=title, abstract, heading word, table of contents, key concepts]
4. ("oral dysaesthesia" or "oral dysesthesia").mp. [mp=title, abstract, heading word, table of contents, key concepts]
5. ("temporomandibular$" or "temporo-mandibular").mp. [mp=title, abstract, heading word, table of contents, key concepts]
6. tmj.mp. or tmd.ti,ab. [mp=title, abstract, heading word, table of contents, key concepts]
7. (myofascial and (pain$ or disorder$ or dysfunction$)).mp. [mp=title, abstract, heading word, table of contents, key concepts]
8. (myofacial and (pain$ or disorder$ or dysfunction$)).mp. [mp=title, abstract, heading word, table of contents, key concepts]
9. (atypical and odontol$).mp.
10. (atypical and toothache$).mp.
11. (atypical and "tooth pain").mp. [mp=title, abstract, heading word, table of contents, key concepts]
12. "phantom tooth pain".mp.
13. (atypical and "facial pain").mp. [mp=title, abstract, heading word, table of contents, key concepts]
14. (atypical and "facial neuralgia").mp. [mp=title, abstract, heading word, table of contents, key concepts]
15. or/1-14
16. exp BEHAVIOR THERAPY/
17. PSYCHOTHERAPY/
18. AUTOGENIC TRAINING/
19. exp COUNSELING/
20. SOCIAL SUPPORT/
21. ("behaviour therap$" or "behavior therap$").mp. [mp=title, abstract, heading word, table of contents, key concepts]
22. counsel$.mp.
23. "autogenic train$".mp.

24. (psychotherap$ or psychoanal$).mp. [mp=title, abstract, heading word, table of contents, key concepts]
25. ("self-help group" or "self help group" or communicat$ or educat$ or inform$).mp. [mp=title, abstract, heading word, table of contents, key concepts]
26. or/16-25
27. 26 and 15

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 adj allocat$).mp.
8. ((singl$ 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

HISTORY

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CONTRIBUTIONS OF AUTHORS

- Vishal R Aggarwal - conceived the idea, conducted the review and prepared it for publication.
- Hanieh Javidi - contributed to the protocol and pilot work leading onto it and drafted the search strategy.
- Sarah Peters - provided expertise in psychological aspects of the review, participated in data extraction and preparing the review for publication.
- Amy Joughin - participated in data extraction and preparing the review for publication and provided input from a primary care perspective.
- Karina Lovell - participated in data extraction and preparing the review for publication.
- Joanna Goldthorpe - participated in data extraction and preparing the review for publication.

DECLARATIONS OF INTEREST

There are no known conflicts of interest to declare.

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INDEX TERMS

Medical Subject Headings (MeSH)

Biofeedback, Psychology [*methods]; Chronic Pain; Cognitive Therapy [*methods]; Facial Pain [psychology; *therapy]; Randomized Controlled Trials as Topic; Temporomandibular Joint Disorders [psychology; *therapy]

MeSH check words

Adult; Humans