The Efficacy of Occlusal Splints in the Treatment of Bruxism: A Systematic Review

Abstract

Objectives

Bruxism is a commonly reported oral parafunctional activity characterised by excessive tooth grinding or clenching outside normal functional activity. The present systematic review aims to examine the available literature to determine the effectiveness of occlusal splints in the treatment of bruxism compared to no treatment and alternative treatment modalities.

Data

Data extraction was undertaken in conjunction with quality of evidence assessment.

Sources

A literature search of the following databases was undertaken: MEDLINE via OVID, Pubmed (Medline), Cochrane Oral Health Group's Trials, The Cochrane Central Register of Controlled Trials and EMBASE.

Study Selection

Randomised Controlled Trials (RCT) and quasi-RCTs which met the inclusion criteria were selected for analysis. These included studies comparing occlusal splints to no treatment or other interventions.

Results

Twenty-two studies were identified for review with fourteen meeting the inclusion criteria. Only a small number of studies were available in each comparison (one or two for some) all of which had a medium to high risk of bias.

Conclusions

There is insufficient evidence to determine whether occlusal splint therapy for the treatment of bruxism provides a benefit over no treatment, other oral appliances, TENS, behavioural or pharmacological therapy. Furthermore, there is a lack of studies in each comparison with many suffering from a high risk of bias. There is a need for further research in this area and improvement in trial quality.

Clinical Significance Statement

This systematic review aimed to determine the effectiveness of occlusal splints in the treatment of bruxism. It found there was insufficient evidence to recommend occlusal splint therapy over no treatment or other treatment modalities. This is relevant to dental clinicians who may provide such appliances and cautions them in treatment provision.

Introduction

Occlusal splints are commonly prescribed for the treatment of patients with bruxism. Bruxism is a commonly reported oral parafunctional activity characterised by excessive tooth grinding or clenching outside normal functional activity [1]. However, there is much debate amongst dental clinicians as to their effectiveness and whether they form an appropriate part of a treatment regime for this condition. Professional opinion is often strong on both sides of the argument but there is a lack of systematic review level evidence. Previous reviews such as the 2007 systematic review by the Cochrane Collaboration [2] found insufficient evidence to affirm the use of occlusal splints in bruxism therapy. A recent systematic review published during editing of the present review had similar findings and did not find evidence to support splint use for temporomandibular disorders or bruxism [3].

The aim of this systematic review is to search the available evidence concerning the effectiveness of occlusal splints in the treatment of bruxism compared to no treatment and alternative treatment modalities. Furthermore, it will assess the quality of, and critically appraise, the available evidence to determine whether there is sufficient justification from the literature to support the use of occlusal splints in the treatment of bruxism to guide clinicians in treatment planning and their decision making.

Methods

The present systematic review was undertaken in the following manner.

Data

Data extraction was undertaken in conjunction with quality of evidence assessment. The search terms used were a combination of free text and mesh terms (see Table 1).

Sources

A search of the literature to 1st April 2019 was undertaken of the following databases: MEDLINE via OVID, Pubmed (Medline), Cochrane Oral Health Group's Trials, The Cochrane Central Register of Controlled Trials and EMBASE.

Study Selection

Randomised Controlled Trials (RCT) and quasi-randomised RCTs which compared occlusal splint therapy to no treatment, placebo, alternative appliance treatment, pharmacological or behavioural treatments were selected for analysis. Both authors independently assessed the studies identified by the search together with the extracted criteria presented below. Where there were any disagreements on study eligibility or interpretation of the characteristics presented, these were discussed between the two authors and resolved. The inclusion and exclusion criteria are presented in Table 2.

Clinical interventions were identified during the literature review which have been used as treatment options for bruxism. These include no treatment, placebo, other intra-oral appliances, cognitive behavioural therapy (CBT), pharmacological therapy and Transcutaneous Electrical Nerve Stimulation (TENS).

Primary outcomes evidence of continued bruxism as measured by frequency of episodes of bruxism (at least 2 episodes, detected by polysomnography and EMG), frequency of grinding noise (at least 2 episodes, detected by polysomnography) and indices of motor activity (at least 2 episodes, detected by electromyography (EMG), electroencephalography (EEG), polysomnography).

Secondary outcomes associated with effects of bruxism but not primary indictors of bruxism activity were also identified. These included (measured using ordinal scale or self-reported): tooth wear, sleep time, quality of life, stress, anxiety, depression, orofacial pain and temporomandibular joint (TMJ) pain.

A PICOS table was generated and is presented in Table 3.

Search Methodology

The search sequence is illustrated in Figure 1. The studies which were excluded from the present study and the reason for their exclusion are presented in Table 4. The characteristics of the included studies are presented in Table 5.

Method of Critical Appraisal

Fourteen studies meeting the inclusion criteria for inclusion in the review were individually assessed for methodological quality using the ’25 point’ CONSORT checklist [4] of included information in reporting a randomised trial.

Some data included in the analysis of the included studies by the CONSORT statement analysis was gained through direct author contact or by author contact by previous similar systematic review authors [2] where the reported study methodology was incomplete or unclear.

Following the detailed analysis using the CONSORT statement, the studies were assessed for evidence quality using the GRADE criteria [5]. Studies were determined as either being of high, moderate, low or very low quality using the GRADE four-point scale.

The studies were assessed using the following Grade Criteria as advised by the Cochrane Collaboration [6]**:**

1) Risk of bias
2) Inconsistency of results
3) Indirectness of results as applied to review question
4) Imprecision – effect size
5) Publication bias

Evidence quality was downgraded from high by one level if serious concern was present regarding one or more of the above criteria. If there was very serious concern, this was downgraded by two levels.

It was determined that evidence quality could be upgraded based on the following:

1. Magnitude of Effect (large)
2. Dose Response
3. Effect of confounding factors would be to reduce effect or be a spurious effect.

It was accepted that upgrading evidence quality was very unlikely for RCTs and thus for the present review. Table 6 shows the GRADE assessment of the studies included in the present review.

Results

Twenty-two studies were identified for review. Fourteen studies met the inclusion criteria and were assessed using the primary and secondary outcome measures outlined. The results of each included study are summarised as follows:

<u>Studies comparing occlusal splints to no treatment</u>

Two studies compared occlusal splints to no treatment.

Hachmann *et al.* [7] compared the increase in size of wear facets in children diagnosed with bruxism in a control group compared to an occlusal splint. The study found no increase in size of wear facets in the intervention group in comparison to an increase in size in the control group. This was, however, not statistically significant (Risk Ratio (RR) 0.20 (95% Confidence Interval (CI), 0.03 to 1.15).

Takahashi *et al*. [8] investigated the comparison between palatal and stabilisation splint therapy to no intervention by assessment of masseter muscle activity (MMA) by EMG, EEG and sleep quality (as determined by sleep assessment). Three groups were analysed: baseline (no treatment), subjects with greater than two bruxism

episodes per hour (high group) or less than this (low group). In the high group, there was a statistically significant reduction in the median number of MMA events per hour ($P<0.01$); 3.14 at baseline, 1.80 for palatal splints, 0.41 for stabilisation splints. Again, statistically significant differences were seen in this group for anxiety outcomes (measured by State Trait Anxiety Inventory-trait (STAI) scoring. The change in number of MMA events in the low group was not statistically significant nor were STAI outcomes. In terms of sleep stage analysis by EEG, no statistically significant differences were seen between the three groups. A positive correlation was determined at baseline between Chromogranin-A levels and STAI scores.

Studies comparing occlusal splints to TENS

Alvarez-Arenal *et al*. [9] compared a mandibular occlusal splint to TENS for outcomes of clicks during TMJ opening/closing and TMJ pain and headaches. Neither intervention demonstrated a statistically significant reduction in the measured outcomes compared to the baseline.

Studies comparing occlusal splints to another intra-oral appliance

Dubé *et al*. [10] compared an occlusal splint to a palatal control device by measurement of number of sleep bruxism episodes per hour and sleep bruxism bursts per hour, episodes with noise, respiratory variables by polysomnography. A statistically significant reduction in number of episodes per hour (41% reduction, $P=0.05$) and bursts per hour (40% reduction, $p<0.05$) was found for both interventions. Similarly, episodes with grinding noise reduced by 50% ($p=0.06$) for both devices. No change was found for respiratory variables. No statistically significant difference could be found between both devices.

Van der Zaag *et al.* [11] compared occlusal (stabilisation splint) and palatal splints (acrylic palatal coverage) by assessment of MMA. Outcomes of number of bruxism episodes per hour, bursts per hour and bruxism time index and sleep variables were measured. No statistically significant differences were found for sleep variables or bruxism variables for either splint type. Some patients experience increases or

decreases in their individual bruxism variables but no statistically significant differences were found between treatment groups.

Landry *et al.* [12] compared an adjustable mandibular advancement appliance (MAA) to baseline and a mandibular occlusal splint for outcomes of episodes of sleep bruxism per hour and sleep bruxism variables. It was found that the mean number of bruxism episodes per hour with MAA usage was reduced from baseline by 39% (at 25% protrusion) and 47% (at 75% protrusion). This was statistically significant (P<0.04). The occlusal splint demonstrated a slight reduction in episodes per hour (34%) which was not statistically significant (P=0.07). Both devices demonstrated statistically significant reductions in bruxism bursts per hour and episodes with noise.

Baad-Hansen *et al.* [13] compared a nociceptive trigeminal inhibitory splint (NTI) with an occlusal splint by EMG events per hour. The NTI showed a significant difference (9·2 ±3·2 events/hour) compared with baseline (19·3 ±4·0; P=0.04). The occlusal splint did not show a significant difference (16·2 ±4·7) to baseline (19·2 ±4·1; P=.716). Neither intervention had a statistically significant effect on clinical outcome measures (pain on palpation *etc.*) (P>0.194).

Landry-Schönbeck *et al*. [14] compared a MAA with baseline and an occlusal splint. Sleep bruxism episodes per hour reduced by 39% and 47% (at 25% and 75% protrusion) (P<0.04) from baseline values with measurement by polysomnography. The number of episodes was reduced with the occlusal splint but was not statistically significant (34%, P=0.07).

Dalewski *et al*. [15] compared an occlusal splint to an NTI for outcomes of EMG activity in postural activity, muscle asymmetry, maximum voluntary contraction of superficial temporal and masseter muscles by surface electromyography. Neither device demonstrated a statistically significant change in the assessed outcomes after 1 month of treatment.

Singh *et al.* [16] compared a maxillary occlusal splint to an MAA. Sleep quality was assessed by the Pittsburgh Sleep Quality Index (PSQI) and sleep bruxism activity by

polysomnography of the masseter. A statistically significant change was found in PSQI index scores for the MAA from baseline (11.20 ±2.11) to 3 months (5.60 ±0.51) and for the occlusal splint (10.07 ±1.18) to (6.40 ±1.07) (P=0.05). Episodes of sleep bruxism were reduced for the MAA from 7.96 ±1.59 to 1.66 ±0.21 at 3 months (P<0.01) and for the occlusal splint from 7.18 ±1.09 to 3.60 ±.55. The MAA was more effective. Bursts were reduced for the MAA from 53.94 ±11.29 to 5.80 ±1.03 at 3 months (P<0.01) and for the occlusal splint from 53.84 ±12.10 to 16.80 ±4.52. Again, the MAA was more effective.

Castroflorio *et al*. [17] compared clear orthodontic aligners and occlusal splint to a placebo splint. They found that subjects using an occlusal splint showed significantly lower numbers of masseter contractions compared to the placebo splint group (MD -29.11, S.E. 11.74, P=0.017). Phasic and tonic contractions were higher after 3 months and during all 6 months respectively. Phasic contractions were similar for clear aligners but there was so statistically significant difference between the three groups for sleep bruxism index.

Studies comparing occlusal splints to behavioural therapy

Ommerborn *et al.* [18] compared cognitive behavioural therapy (problem-solving, muscle relaxation, nocturnal biofeedback, recreation and enjoyment training) to an occlusal splint. Participants were assessed pre-treatment, post-treatment, and at a 6-month follow-up for sleep bruxism activity, self-assessment of sleep bruxism activity and associated symptoms, psychological impairment, and individual stress-coping strategies. The analyses demonstrated a significant reduction in sleep bruxism activity (Bruxism sleep monitoring device), self-assessment of sleep bruxism activity, psychological impairment and positive stress-managements strategies. Bruxism activity, self-reported bruxism activity and psychological impairment all reduced from pre-treatment to 6-month follow-up and positive stress management strategies increased over the same period. The effects were however small and there were no statistically significant differences between interventions.

Studies comparing occlusal splints to pharmacological therapy

Madani *et al*. [19] compared an occlusal splint to pharmacological therapy with Gabapentin. Polysomnography was used to record sleep bruxism and sleep variables for both groups. Statistically significant reductions in bruxism variables (episodes per hour and per night, duration of episodes (bruxism time index), total duration per night and number of episodes during sleep stages (NR I and II) were demonstrated for both groups post-treatment ($P<0.05$). There was no statistically significant difference between groups. Gabapentin showed improvement in sleep variables ($P<0.05$) which was not seen in the occlusal splint group.

Studies comparing occlusal splint wear patterns

Matsumoto *et al.* [20] compared intermittent occlusal splint wear to continuous use over a 4-week period. Outcomes of number, duration and total activity for sleep bruxism were assessed by electromyography. With continuous use, masseter electromyographic events were reduced (statistically significantly) immediately and at 1 week. Episode duration was reduced immediately but not at further observation at 2, 3 and 4 weeks ($P<0.05$). With intermittent wear, masseter electromyographic events were reduced in number and duration (statistically significantly) both at immediate analysis and at 4 weeks ($P<0.05$). Intermittent use appeared to show a greater reduction in bruxism variables than continuous use.

Critical appraisal of included studies

Overall evidence quality of included studies was low to moderate, with nine studies being assessed as ‘moderate’ quality and five being ‘low’ quality as per GRADE assessment. Methodological issues with potential for bias introduction were the primary cause of downgrading of evidence quality.

Allocation and randomisation was overall poorly reported and described. Allocation and randomisation is essential in preventing selection bias and baseline differences which could be statistically significant. This is important to maintain the internal validity of the study and to determine that differences observed between interventions are not due to other variables. All studies designs were described as randomised controlled trials except for Hachmann *et al*. [7] which was quasi-

randomised. Takahashi *et al.* [8]; Alvarez-Arenal *et al*. [9]; Dubé *et al*. [10]; Landry *et al.* [12]; Baad-Hansen *et al*. [13] and Landry-Schönbeck *et al*. [14] employed a cross-over design. Only five of the included studies showed adequate description of allocation/randomization [10,11,12,15,16]. Allocation concealment was unclear for four studies [7,9,14,18] and not described at all for the remainder. Description of allocation concealment/sequence generation for all studies, even where deemed adequate, was incomplete. Further information was obtained both by direct author contact and from previous contact by systematic review authors [2] but it was still not possible to obtain the full remit of required information.

Blinding was similarly poorly reported and described. Blinding of participants and observers aims to reduce the risk of biased estimates of treatment effect. This can occur due to differences in treatment between intervention groups or differential assessment and reporting of outcomes. Blinding aims to limit this risk of bias. Five studies did not report blinding [8,14,16,18,19], six were single-blinded [7,9,13,15,17,20] and only three were double-blinded [10,11,12].

Losses to drop-outs and follow-up was another aspect that was generally poorly described and reported. This is another area where potential bias can be introduced as there is a risk of differential drop-outs between groups and patients who remain in the study may have different characteristics to those who drop-out. Analysis and accounting for losses is essential to prevent bias introduction during the study process. Only four studies adequately reported both drop-outs and losses to follow-up [7,16,17,20]. Losses to drop-out only were adequately described for a further three studies [9,10,12]. Landry *et al.* [12] and van der Zaag *et al.* [11] did report drop-outs but this was unclear and did not demonstrate intention to treat analysis. For the remaining studies, no indication was given whether all participants completed the initial study or follow-up as appropriate.

Determination of sample size was poorly reported in most studies. Sample sizes were low for many studies e.g. ten or less [7,10,13]. More recent studies demonstrated generally larger sample sizes. Reporting of sample size determination is essential for the reader to interpret study quality. An inadequate sample size may produce inconclusive results with unnecessary participant exposure to the

intervention, too large a sample may expose too many participants and be wasteful of available resources. An appropriate sample size is necessary to obtain valuable information and for ethics. The method of sample size determination was; however, only adequately described in two studies [14,17]. Power calculations were not described in most studies.

Indication of effect size was a significant area that was lacking in all studies. None of the included studies gave clear indicators of effect size so while there may have been suggestion that an intervention was effective (significant or low P value), it was unclear to what degree it was effective. Indicators of precision of effect size e.g. 95% confidence intervals were only reported in one study by Hachmann *et al.* [7]. It appears, given the small sample sizes, that effect size is likely limited for most studies.

This study aimed to determine whether sufficient justification can be elicited from the literature to support the use of occlusal splints in the treatment of bruxism. The systematic literature search undertaken, although generating 434 potentially relevant papers, only 22 were deemed suitable for abstract review and of these, 14 met the inclusion criteria. Thus, from the outset, the available dataset is limited. Excluded studies were either non-randomised clinical trials or demonstrated significant methodological flaws which merited exclusion.

The included studies, although meeting the inclusion criteria for analysis, still demonstrated significant methodological issues and all were assessed as being of either low or moderate quality. Description of allocation and randomisation was generally poor and incomplete despite author contact for clarification. Poor implementation and reporting of blinding further contributed to bias risk. Small sample sizes with poor reporting of withdrawals and losses to follow-up meant that estimation of effect size, precision of effect size and thus assessment of external validity of findings was limited. Study design was also suboptimal. Many studies used a crossover design but did not fully report washout periods making assessment of intervention effect difficult.

It was notable during analysis that the method of diagnosis of bruxism differed greatly between studies and this may affect the likelihood of a definitive, comparable initial diagnosis. A grading system for bruxism based on diagnostic method has been described by Lobbezoo *et al*. [1] and this was applied to the included studies in this review. Some studies included participants with possible awake/sleep bruxism with diagnosis based on 'self-reporting' (Grade 1). Some studies had participants with probable awake/sleep bruxism, diagnosed using a positive clinical inspection (with or without self-reporting) (Grade 2). Other studies had participants with definite awake/sleep bruxism, diagnosed using a positive instrumental result. (with or without self-reporting) (Grade 3). The included studies were graded using the method outlined and the findings are presented in Table 6. This variation in diagnostic process again made study comparison difficult given the potential for variation in the diagnostic probability of true bruxism.

The interventions differed between studies making comparison difficult. While the majority of studies used a maxillary stabilisation type splint, Alvarez-Arenal *et al*. [9] utilised a mandibular splint. Control appliances also varied with Dubé *et al.* [10] and van der Zaag *et al*. [11] utilising more unusual palatal control devices. This may affect the external validity of these study findings. This may also be affected by the differences in method of outcome assessment between studies such as sleep variables, bruxism indices, patient reporting of symptoms, visual scales (comfort), participant preference, plaster models and clinical examination. Many studies demonstrated little significant difference between outcomes. Lack of assessed outcome consistency between different studies, varying methods of outcome assessment and small sample sizes mean that studies were generally underpowered. This may mean that although findings may be determined as significant for the small sample groups, extrapolation of these findings to a population level may result in favouring the null hypothesis.

Discussion

The studies analysed allow comparison of occlusal splints to no treatment, TENS, other oral appliances, behavioural therapy and pharmacological therapy and give insight into the effect of wear patterns on therapeutic effect.

Studies that investigated splint therapy compared to no treatment gave mixed results with no statistically significant effect on prevention of wear progression in children with sleep bruxism [7] but there was suggestion that in patients with high frequency bruxism activity, that occlusal splints may reduce the number of 'bursts' when compared to no treatment [8]. Unfortunately, only two studies with a high risk of bias were present in this comparison with small sample sizes (23 and 9 respectively, of which the latter were children) so insufficient data is available to arrive at any meaningful conclusion.

Of interest, was the comparison to alternative oral appliances. No significant difference was noted between occlusal splints and a palatal control device [10]. Similar results were found for palatal splints [11]. Mandibular advancement appliances; however, appeared to demonstrate an advantage over occlusal splints with Landry *et al*. [12] finding that when compared to MAA, the reduction in episodes of bruxism activity was not reduced significantly for occlusal splints. Bursts were reduced significantly. The MAA produced significant results for both outcomes. [17,14] had similar findings with statistically significant reduction in bruxism episodes for the MAA but not for the occlusal splint. Singh *et al*. [16] also compared MAA to occlusal splints and although they found an improvement in sleep quality for both interventions and reduced frequency of bruxism episodes and bursts, the MAA was more effective for all outcomes. When nociceptive trigeminal inhibitory splints were compared to occlusal splints, Baad-Hansen *et al*. [13] found that while the NTI gave a significant reduction in bruxism events per hour, this was not statistically significant for the occlusal splint. Dalewski *et al*. [15] in a similar study found neither device demonstrated a significant effect. When compared to a placebo splint and clear orthodontic aligners, the occlusal splint demonstrated a decrease in masseter contractions long-term but no significant difference was found between interventions for sleep bruxism variables.

When compared to non-appliance therapeutic options, such as TENS, both treatments gave no statistically significant effect on bruxism activity and there was no difference between the treatments [9]. CBT and occlusal splints were both found to significantly reduce sleep bruxism activity by Ommerborn *et al*. [18] but no

statistically significant difference was found between interventions. When Gabapentin therapy was compared to an occlusal splint, no difference was detected between interventions in reduction of sleep bruxism variables. Both interventions showed statistically significant therapeutic reductions but the effects were small.

Matsumoto *et al*. [20] found intermittent wear was preferable to continuous wear in reduction in bruxism variables. The available evidence has exposed the inherent difficulties in assessing treatment modalities in this area. Previous treatments have been often provided based on clinical opinion with little or no high-quality evidence. There are many possible interventions to compare: a myriad of splint designs/types and many different possibilities for both pharmacological and behavioural therapy. This makes definitive comparison between interventions difficult. Reporting of effects is also complex with many different methods: polysomnography, EMG, self-reporting of bruxism episodes and analysis of tooth-wear on models. The wide variety makes difference in effect between treatments difficult to report. Study protocol is difficult, as due to the nature of the interventions, blinding can never be satisfactorily achieved as the participant will always be aware of the type of intervention and this may affect how they perceive and report effects. A similar situation will apply to examiners and observers.

The follow up periods in the included studies were all of a short duration with many studies not having any follow up at all. The longest follow up period was six months, although one did include a telephone consultation after twelve months. It would have been advantageous to have longer follow up periods for these patients to examine whether the outcome changed over the long term.

Conclusions

The present systematic review has shown that there is insufficient data to affirm the effectiveness of occlusal splints in the treatment of bruxism when compared against no treatment, other intra-oral appliances, TENS, CBT or pharmacological management. This is due to the lack of studies in each comparison and with many suffering from a high risk of bias. There is a need for high quality research work in this area.

Recommendations for future studies

The present study has highlighted the need for further research in this area and improvement in trial quality. Well-designed randomised controlled trails following guidance such as CONSORT are essential to provide clear and effective evidence to answer this much needed research question. Future research should aim to simplify the research question by assessing efficacy of interventions for a specific condition (and with clear inclusion and exclusion criteria) rather than attempting to cover a variety of conditions, for example, temporomandibular disorder, bruxism, masticatory muscle activity etc. There is a need for clarity in the diagnostic process of participants included in the studies as the probability of the presence of true bruxism is unclear. Inclusion of further intervention groups in studies with appropriate sample and effect size and longer follow-up periods will enable better comparison of intervention effect. Further studies should have a consistent method in trial design for participant bruxism assessment and diagnosis as described by Lobbezoo *et al.* [1,29].

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Tables

Table 1

1	‘Sleep AND Bruxism’
2	‘Bruxism’
3	‘Bruxist’ ‘Teeth AND Grinding’
4	‘Teeth AND Grind’
5	“Tooth AND Grinding’
6	‘Tooth AND Grind’
7	‘Teeth AND Clenching’
8	‘Teeth AND Clench’
9	‘Tooth AND Clenching’
10	‘Tooth AND Clench’
11	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10
12	‘Splint’
13	‘Splints’
14	‘Occlusal AND Splint’
15	‘Occlusal AND Splints’
16	‘Bite-splint’
17	‘Bite AND Splint’
18	‘Oral AND Appliance’
19	‘Bite AND Raising AND Appliance’
20	‘Bite-plate’
21	‘Bite AND Plate’
22	‘Michigan AND Splint’
23	‘Tanner AND Splint’
24	12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23
25	11 and 24

Table 1 Search Terms

Table 2

	Inclusion criteria	Exclusion criteria
Study Design	RCTs or quasi-randomised controlled trials	Case series, case studies, editorials or expert opinion
Participants	Human studies of adults and children (older than 1 year of age)	Participants with comorbidities such as unrelated movement, neurological or psychiatric conditions.
Sample size	n ≥ 5 participants	n < 5 participants
Observation periods	All periods of observation	
Diagnosis	Clinical diagnosis of bruxism, tooth-grinding or clenching and/or polysomnography	
Problem specification		If not clearly addressed
Primary outcome		If not reported or addressed
Language	English language only	Not in the English language

Table 2 Inclusion and exclusion criteria.

Table 3

Population	child (1+), adult, aged (65+), sleep bruxism
Intervention	occlusal splint
Comparison	No treatment, placebo, other intra-oral appliances, CBT, pharmacological therapy, TENS
Outcome	frequency of episodes of bruxism, frequency of polysomnographically detected episodes and indices of motor activity detected by EMG, EEG and polysomnography
Sources	RCTs or quasi-randomised controlled trials

Table 3 PICOS table generated to detail and define the key components of the research question.

Table 4

Study	**Reason for Exclusion**
Keskinruzgar *et al.* [21]	Cannot access and unable to obtain copy from author
Trindade *et al*. [22]	Non-randomized clinical trial
Carra *et al.* [23]	No appropriate control
Ghanem [24]	Non-randomised clinical trial
Harada *et al.* [25]	Inappropriate date recording and reporting
Castroflorio *et al.* [26]	Non-randomised clinical trial
Roark *et al.* [27]	Non-randomised clinical trial
Raphael *et al.* [28]	No inclusion criteria given

Table 4 Studies excluded from the present study and the reason for their exclusion.

Table 5

	Methods / Study Design	Blinding	Allocation sequence	Participants, n=	Follow up time	Losses to follow-up	Interventions	Outcomes	Bias Risk
Castroflorio *et al.* (2018) [17]	3 arm parallel group RCT	Recording analysis operator blinded to study aims	Not described	60	No follow-up after end of 6 month analysis period.	0	Clear aligners, maxillary occlusal splint with bite plane, placebo maxillary splint	Sleep bruxism (SB) episodes per hour, tonic/phasic masseteric contractions using electromyographic-electrocardiography monitoring.	Moderate No description of allocation concealment and randomization
Singh *et al.* (2015) [16]	RCT	No blinding described	Described	36	No follow-up after end of 3 month analysis period.	4 excluded due to comfort / aesthetic issues 4 lost to follow-up	Mandibular advancement device, maxillary occlusal splint	Sleep quality using Pittsburgh Sleep Quality Index, Sleep bruxism activity using electromyographic (EMG) activity of masseter using polysomnography.	Moderate Sample bias and small size Effect size limited
Dalewski *et al.* (2015) [15]	RCT	Semi-blinded: the examiner conducting measurements was blinded regarding procedure type and the currently examined patients' group	Described	30	No follow-up.	Not described	Occlusal splint, modified nociceptive trigeminal inhibition splint (Lucia Jig)	EMG activity in postural activity, maximum voluntary contraction of superficial temporal and masseter muscles.	Moderate Effect size limited
Matsumoto *et al*. (2015) [20]	RCT	Examiner blinded to subject's intervention group.	Described	20	No follow-up.	0	Continuous and intermittent wear of occlusal splint	Number and duration of nocturnal masseteric EMG events per hour compared with total EMG activity	Moderate Effect size limited
Takahashi *et al*. (2013) [8	Crossover RCT	Allocation concealment not given	Not described	23	No follow-up.	Not described	With and without stabilization splint wear	Masseter EMG activity during sleep. Psychological analysis using Japanese	High No allocation concealment

								version of the 'State-Trait Anxiety Inventory' which consists of two scales: 20-item state anxiety (STAI Y-1 scores) and trait anxiety (STAI Y-2 scores) scales. Measurement of salivary Chromogranin A	
Madani *et al*. (2013) [19]	Single-blind, RCT	Not described	Concealment not given	24	No follow-up.	4 excluded during study. Drop-outs and loss to follow-up not described.	Stabilization splint and Gabapentin	Episodes of sleep bruxism per hour and per night, bruxism time index and duration of sleep bruxism episodes by polysomnography	High Inadequate allocation concealment
Landry-Schönbeck *et al*. (2009) [14]	Short-term randomized crossover controlled experimental study	Not described	Concealment not clear	12	No follow-up.	1	Mandibular occlusal splint (control), mandibular advancement appliance	Episodes of sleep bruxism per hour by polysomnography	Moderate Inadequate allocation concealment
Ommerborn *et al*. (2007) [18]	Two-group randomized, treatment comparison trial with a pre-treatment, post-treatment, and a 6 month follow-up controlled design	Not described	Concealment not clear	77	6 months	20	Maxillary occlusal splint, cognitive-behavioural therapy	Sleep bruxism activity (Bruxcore bruxism monitoring device), self-reported sleep bruxism activity and symptoms, psychometric stress-coping questionnaire	Moderate Inadequate allocation concealment No blinding
Baad-Hansen *et al*. (2007) [13]	Randomized cross-over study	Investigator blinded	Not described	10	No follow-up.	Not clear	Nociceptive trigeminal inhibitory splint, standard flat occlusal	Masseter EMG activity – number of episodes of activity per hour of sleep.	High Inadequate allocation concealment

							stabilization splint		and randomization.
Landry *et al*. (2006) [12]	Randomized, controlled cross-over study	Blinding of data extractors and data analyzers	Concealment and randomization not published but obtained by author communication	13	No follow-up.	Not described	Occlusal splint, Mandibular advancement device in 25%, 50% and 75% advance positions and in free position	Sleep bruxism episodes per hour of sleep, sleep latency, number of orofacial activities, pain during the night, oral dryness, comfort, preference	Moderate Allocation concealment not fully described
van der Zaag *et al.* (2005) [11]	Controlled, randomized clinical study	Blinding of data extractors and patients	Concealment not published but obtained by author communication	21	No follow-up.	Not clear	Occlusal splint, palatal splint	Number of bruxism episodes per hour of sleep, total sleep time, sleep efficiency, arousal index	Moderate Allocation concealment not fully described. Poor reporting of withdrawals
Dubé *et al.* (2004) [10]	Randomized, controlled cross-over study	Blinding of data extractors and data analyzers	Some randomization. Information obtained by author communication	9	Telephone follow-up only at 1 year.	No drop-outs. Follow-up not reported.	Occlusal splint, palatal splint	Sleep efficiency, arousal index, awakenings per hour, number of episodes with noise, preference, comfort	Moderate Allocation concealment not fully described.
Alvarez-Arenal *et al.* (2002) [9]	Randomized, controlled cross-over study	Blinding of data collectors	Not clear	11	No follow-up.	No drop-outs. Follow-up not reported	Occlusal splint, TENS	Clicks recorded in temporomandibular joints (TMJ) during opening and closing, TMJ pain, headache	High Allocation concealment not clear
Hachmann *et al.* (1999) [7]	Quasi-randomized, controlled study	Blinding of data collectors	Not described	9 (Children age 3-5)	6 months	0. No drop-outs or losses to follow-up	Occlusal splint, no treatment	Increase in the size of wear facets (canine teeth) by visual inspection of stone models at end of treatment and 6-month follow-up	High No allocation concealment

Table 5 The characteristics of the included studies.

Table 6

Study	Level of Quality
Castoflorio *et al.* [17]	Moderate
Singh *et al*. [16]	Moderate
Dalewski *et al*. [15]	Moderate
Matusomoto *et al*. [20]	Moderate
Takahashi *et al*. [8]	Low
Madani *et al*. [19]	Low
Landry-Schonbeck *et al*. [14]	Moderate
Ommerborn *et al*. [18]	Moderate
Baad-Hansen *et al*. [13]	Low
Landry *et al*. [12]	Moderate
Van der Zaag *et al*. [11]	Moderate
Dube *et al*. [10]	Moderate
Alvarez-Arenal *et al*. [9]	Low
Hachmann *et al.* [7]	Low

Table 6 GRADE assessment of included studies.

Figures

Figure 1

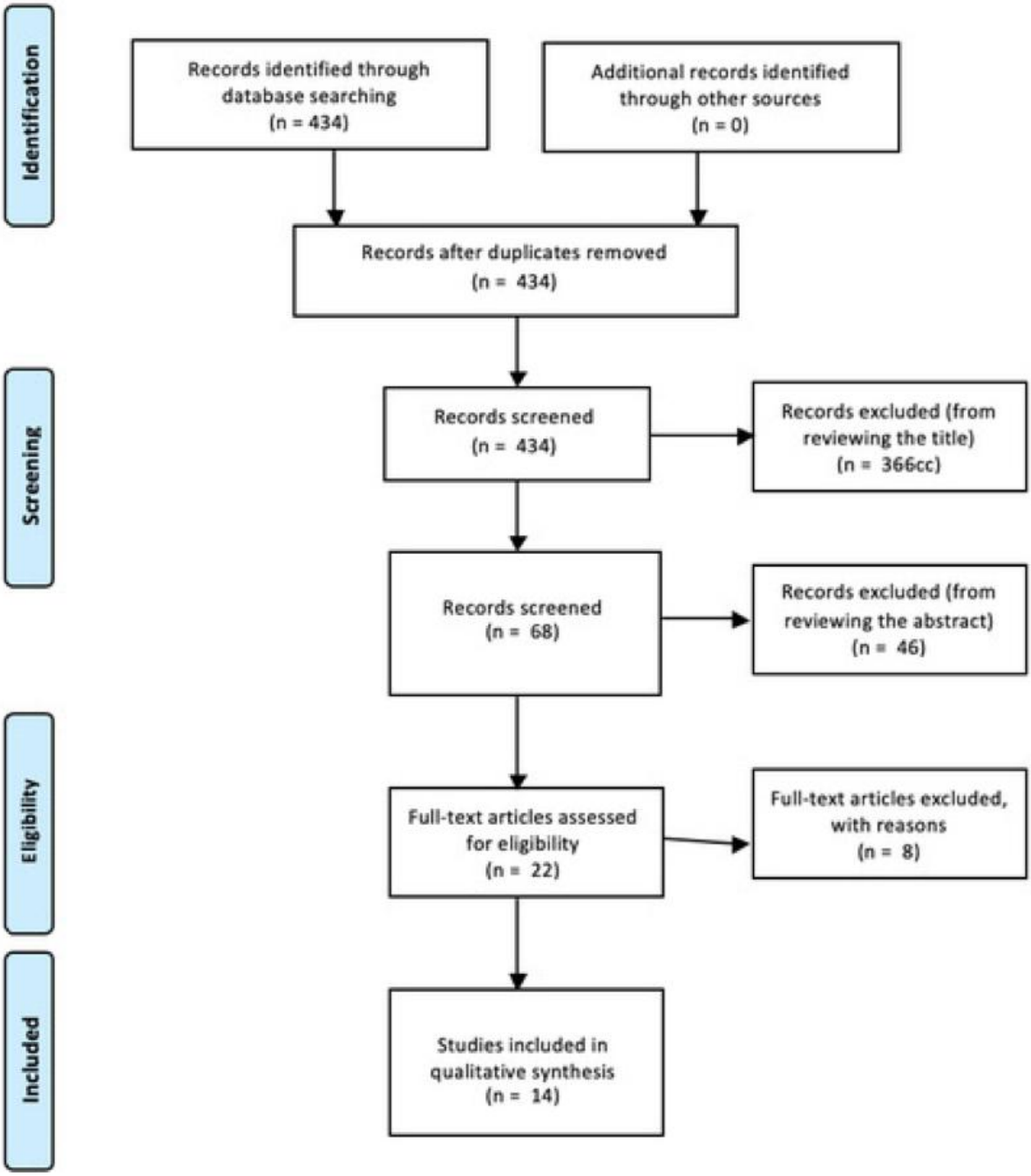

Figure 1 PRISMA flow diagram [30]