Comparison of various treatments for sleep bruxism using determinants of number needed
to treat and effect size

CRD summary
This review concluded that although the mandibular advancement device and clonidine had shown the best results in sleep bruxism, both treatments were associated with side-effects. The authors considered the occlusal splint and clonazepam to be acceptable short-term alternatives, although they recommended further research. The reliability of the review is uncertain, owing to several methodological problems, but the authors’ recommendations for further research appear reasonable.

Authors' objectives
To compare the effectiveness of different treatments for sleep bruxism (SB) in order to determine best options for further research.

Searching
MEDLINE was searched and a recent review was also consulted, in addition to studies carried out at the Centre de Recherche du Sommeil, Hopital du Sacre Coeur, Montreal.

Study selection
Study designs of evaluations included in the review
To be eligible, studies needed to be double-blind randomised controlled trials (RCTs). However, one single-blind RCT was included in the review. Case reports and open studies were excluded. Both parallel-group and crossover trials were included in the review.

Specific interventions included in the review
Eligible studies investigated drug treatments or oral devices compared with a placebo. The treatments used in the included studies comprised drugs (bromocriptine, L-dopa, propranolol, clonidine, clonazepam, tryptophan and amitriptyline) and oral devices (mandibular advancement device (MAD), occlusal splints and palatal splints). Treatment duration ranged from a single dose to 4 weeks.

Participants included in the review
No explicit inclusion criteria were stated. It appeared that studies of participants with SB were eligible for inclusion in the review.

Outcomes assessed in the review
To be eligible, studies needed to use electromyographic recordings. Some studies recorded the electromyographic signal together with polygraphic sleep recordings, whilst others used ambulatory devices.

How were decisions on the relevance of primary studies made?
The authors did not state how the studies were selected for the review, or how many reviewers performed the selection.

Assessment of study quality
The authors did not state how validity was assessed, or how many reviewers performed the assessment.

Data extraction
The authors did not state how many reviewers performed the data extraction.

Where possible, the number-needed-to-treat (NNT) or number-needed-to-harm was calculated for the included studies. The SB indices (SB episode/hour) were extracted. Effect sizes were calculated for all included studies, in terms of the ratio of the mean difference between treatment and placebo of the SB index relative to the standard deviation of that
difference. The power of each study was also calculated.

**Methods of synthesis**

How were the studies combined?
The studies were combined in a narrative.

How were differences between studies investigated?
Differences between the studies were described in the text.

**Results of the review**

Ten RCTs were included in the review.

The best results for oral devices were observed for the MAD, with an effect size of 1.5 and an NNT of 2.17 based on a single study. Two studies found effect sizes of 0.28 and 0.3 for palatal splints, and 2 studies found effect sizes of 0.55 and 0.58 for occlusal splints. Among the pharmacologic trials, clonidine, clonazepam and L-dopa had an effect size of greater than 0.8, whilst all other pharmacological agents had effect sizes of less than 0.3.

**Authors' conclusions**

Although the MAD and clonidine had shown the best results, both treatments were associated with side-effects. The authors considered that the occlusal splint and clonazepam seemed to be acceptable short-term alternatives but further research is needed.

**CRD commentary**

Apart from study design, inclusion criteria for this review were rather unclear. The search was limited, which means that it is more likely that some relevant studies were not included. It was unclear how many reviewers had been involved in each aspect of the review process. If one reviewer selects studies, especially if criteria are not clearly detailed, this may lead to bias and errors; this is also the case with the data extraction. The authors did not report assessing study validity, which makes an assessment of the review conclusions difficult. The narrative synthesis appears appropriate given the diversity of the treatments. However, to demonstrate the superiority of one treatment over another, direct comparisons or formal indirect comparisons are needed, rather than a comparison of effect size in relation to placebo. The reliability of the conclusions is therefore uncertain, although the authors' recommendation for further research appears reasonable.

**Implications of the review for practice and research**

Practice: The authors concluded that although the MAD and clonidine had shown the best results, both treatments were associated with side-effects. They considered that the occlusal splint and clonazepam seemed to be acceptable short-term alternatives.

Research: The authors stated that further, longitudinal, large sample size RCTs in SB management are needed.

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This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.