Oral splints for patients with temporomandibular disorders or bruxism: a systematic review and economic evaluation
Protocol

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Background
Description of the condition
Splint therapy has long been used as a conservative treatment option for patients presenting with certain orofacial signs and symptoms including orofacial pain, joint clicking, limited mouth opening or tooth wear. These are typically patients presenting with a temporomandibular disorder or bruxism.

Temporomandibular Disorders (TMD) are the second most common cause (after dental pain) of orofacial pain, characterized by pain in the temporomandibular joint area and in the facial muscles. Apart from pain patients may experience other signs and symptoms such as clicking of the joint and restricted mouth-opening. It is estimated that around 5% to 12% of the population have TMD symptoms to some degree, varying by age group and gender (NIDCR 2014). There are many ways of managing TMD (such as pharmacological, psychological, physiotherapies and surgical interventions), however one of the most common ways that dentists, particularly in primary care, manage symptomatic TMD is the provision of oral splints (Aggarwal 2012).

Oral splints are also provided to help manage tooth wear caused by bruxism. Bruxism is the repetitive jaw-muscle activity characterized by clenching or grinding of the teeth and /or bracing or thrusting of the mandible. Bruxism has two distinct circadian manifestations: it can occur during sleep (indicated as sleep bruxism) or during wakefulness (indicated as awake bruxism) as recently defined by an international group (Lobbezoo 2013). The prevalence of bruxism ranges from 8 -31% in the general population (Manfredini 2013).

It has been estimated globally that this is a common condition, which affects 16% of the adult population (sleep bruxism) and 24% for awake bruxism (Lobbezoo 2012).

In the UK it has been estimated that bruxism affects more than six million people. The severity of the symptoms and the frequency of grinding varies. It can occur in both children and adults, although it is most common in adults between the ages of 25 and 44. Although many patients are unaware of their bruxism habit there can be an associated chronic low grade tooth wear which can cause pathological damage and require treatment in the longer term. This is often diagnosed by the general dental practitioner (GDP) when the patient is attending for a check-up or for dental treatment. It is important that tooth wear alone is not taken as a sign that the patient is an active bruxist, as opposed to being a legacy of a previous bruxism habit.

Description of the intervention
Oral splints are removable appliances that can cover all or some of the teeth in either the maxillary or mandibular arches. The term "oral splint" is used colloquially in (UK) dentistry and is really a misnomer, as oral splints do not actually splint (i.e. immobilise) anything. Splints can also be known variously throughout the literature and the world as oral appliances, devices, orthotics, or biteplates.

Oral splints can resemble a device similar to a mouthguard used in contact sports, overlaying the biting surface of the teeth with some type of material. Numerous types of oral splints are available, varying in design, material,

coverage and application. Splints either cover the upper teeth (upper splints) or the lower teeth (lower splints) and can be classified by the type of material they are made from: hard - hard acrylics; soft – soft polymers or plastics; composite amalgams of the two aforementioned materials (Klasser 2009). They can then be subdivided into whether they cover all the surfaces of teeth in one jaw (full-coverage), or only some of the teeth surfaces (partial coverage, e.g. covering only the front 6-8 teeth, or 2-4 of the anterior incisor teeth), and whether they provide an adjusted biting surface to equalise the way the teeth meet the splint ('occlusally adjusted' surface) (Clark 2006; Wright 2014). Finally they may be made from impressions of the patient's teeth (custom made) or adapted from a non specific *blank* (prefabricated or non custom made).

It should be noted that there are multiple names for different types of splints, and many variations on a design theme. For example: an upper hard stabilisation splint is also known as a Michigan splint; a Lucia jig is similar in design to the proprietary Nociceptive Trigeminal Inhibition Tension Suppression System (NTI-tss) splint.

Traditionally, oral splints recommended by dentists have been custom made, often in dental laboratories, requiring a number of appointments. More recently, a vast array of prefabricated splints have become available, either for provision by the dentist or healthcare worker at a single appointment, or as over-the-counter purchases for the patients who wish to self-manage their symptoms (Wassell 2014).
Prefabricated splints include soft, rubber splints (which function by separating the teeth), hydrostatic splints which are cushioned with fluid to redistribute occlusal force and the NTI-tss device (semi-customisable).

The duration of treatment, the need for adjustments and the costs of the splints vary across splint types.

How the intervention might work

There is continuing debate about the exact mechanism of action of oral splints. However, mechanisms include:

- muscle relaxation/habit breaking for patients with increased parafunctional or muscle-tightening habits.
- protection of teeth and jaws, particularly where teeth clenching and grinding may lead to damage of teeth,
- resulting in the need for restorative treatment.
- normalizing periodontal ligament proprioception, by utilizing a splint to spread the forces placed on
- individual teeth
- repositioning of the jaws and condyles in to centric relation.

The mode of action varies according to the type of splint used, with some splints (permissive) allowing the teeth/jaw to move or glide over the biting surfaces unimpeded (permissive splints), and others having indentations that hold the jaw in a fixed position (directive or non-permissive).

Why it is important to do this review

This systematic review has arisen from an NIHR HTA call addressing the research question "What is the clinical and cost-effectiveness of prefabricated oral splints and custom-made splints for the treatment of orofacial symptoms?". Our application was successful and we have received funding to conduct this systematic review and economic evaluation, so the objectives of this review have been driven by this (Appendix 1).

It should be noted, the original call focused on treatment for orofacial symptoms . The causes of orofacial pain are varied, but splint therapy for orofacial pain is primarily limited to pain resulting from TMD. Splint therapy is also used for non-painful TMD and bruxism. In order to reflect the use of oral splints in dental practice in the UK, the review will focus on TMD (pain related and non-pain related) and bruxism.

Although we will be using Cochrane methods this will not be undertaken as a Cochrane review, however we will share all data from screening of studies, data extraction forms and correspondence with authors of any future Cochrane reviews, or review updates which overlap with the scope of this review.

Dentists in the NHS in both primary and secondary care are currently providing oral splints for patients who have orofacial signs (such as tooth wear in patients with bruxism) or symptoms (primarily pain). In Scotland alone the number of splints provided in NHS primary care is increasing from 1985 custom made hard splints in 2005/06 to 3521 custom made hard splints in 2015/16. Dentists in Scotland have also recently been allowed to provide custom made soft splints on the NHS and there were 16,888 provided in 2015/16. Oral splints are also provided privately and directly to patients with an evolving growing industry reported (Wassell 2014).

Despite the frequent use of splints for the management of orofacial sign and symptoms their clinical and cost-effectiveness remains uncertain. This research proposal will inform the NHS, dentists and patients as to whether oral splints provided by dentists or other healthcare workers are effective in reducing orofacial symptoms (primarily pain) and when they are indicated to prevent tooth wear. If oral splints are found to be effective, then the effectiveness of prefabricated splints compared to custom-made splints (laboratory made requiring more

than one visit to the healthcare worker to fit), will be evaluated to help inform care pathways for the target population.

If prefabricated splints are found to be at least as effective as custom-made splints, then there is the potential for a cost saving to both the NHS and directly to patients. Currently, in primary care the provision of custom made oral splints for these patients is a Band 3 charge to the patient under the current NHS dental fee scale (around £222). Prefabricated splits are a much cheaper alternative to custom made splints as they require only one visit for fitting compared with two, and no laboratory costs, and are a Band 2 charge in the NHS (£51). Over-the-counter splints can be purchased for less than £10.

Objectives

To evaluate the clinical effectiveness and cost-effectiveness of oral splints for patients with TMD or bruxism.

We will meet our aim by undertaking a comprehensive evidence synthesis, utilizing Cochrane methodology, evaluating:

a) all oral splints provided by dentists or other healthcare workers versus no splints for patients with TMD or bruxism, and

b) prefabricated splints versus custom made splints provided by dentists or other healthcare workers for patients with TMD or bruxism.

Methods

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials but will not include cross-over studies as we do not feel that this is an appropriate design due to the transient nature of the TMD symptoms, or bruxism in patients (which may be due to external factors such as stress).

Types of participants

Inclusion criteria: children (over 11 years) and adults who have either TMD or bruxism, and the dentist or other healthcare worker is considering treating the patient with an oral splint. This will generally include trials on patients with TMD, and trials on patients with bruxism. The patients may be seeing a dentist or other healthcare worker in either primary or secondary care.

Exclusion criteria: studies in which the majority of participants were undergoing fixed or removable orthodontic treatment

Types of interventions

Two comparisons will be made:

1. Splints versus no splints, which will include any type of splint provided for patients outlined above. The no splint group may also include a placebo splint which is used in some trials, watchful waiting/or minimal treatment or self-management.

2. Prefabricated splints versus custom-made splints. No other head to head comparisons will be included between different splint types.

For clarity, we will refer to splints according to: the jaw in which it is used (upper/lower), its material (hard/soft/composite), its degree of coverage of teeth (full/partial), and then its most generic name, unless the proprietary name is particularly pertinent.

Types of outcome measures

Primary outcomes

The primary outcome for the review will be pain. This could be measured in a number of ways including changes in the pain intensity from baseline, end score pain measures or frequency of episodes of pain. Harms will be a primary outcome, which will include any problems such as soreness of the oral cavity caused by the splint.

For bruxism patients, tooth wear will also be considered a primary outcome.

Secondary outcomes

Secondary outcomes will include clicking of the temporomandibular joint, change in restricted mouth opening, frequency of headaches (secondary to pain-related TMD), Quality of Life data (including physical and emotional function), patient satisfaction and adherence to treatment will be collected whenever possible. For bruxism the index and frequency of bruxism activity will also be recorded.

Follow-up periods for the outcome data will be divided into short term follow-up (3 months or less) or medium term (3-12 months) or long term follow-up (more than 12 months).

Search methods for identification of studies

An information specialist has developed a search strategy (see Appendix 2) and will conduct the literature search.

Electronic searches

The following databases will be searched:

- Cochrane Central Register of Controlled Trials (CENTRAL) in the Cochrane Library;
- MEDLINE Ovid (1946 onwards);
- Embase Ovid (1980 onwards);
- CINAHL EBSCO (1937 onwards).

Where appropriate, the searches of these databases will be linked to study design search filters developed by Cochrane for identifying reports of randomized and controlled clinical trials. They will be undertaken without restrictions on language or date of publication.

Searching other resources

Unpublished data on clinical trials will be sought via searches of the US National Institutes of Health trials register (ClinicalTrials.gov) and the WHO International Clinical Trials Registry Platform, which includes trials data from the European Union, the UK, Australia, China, the Netherlands, Brazil, India and Korea. Conference proceedings will be searched via Embase and the Web of Science. Abstracts of dissertations and theses will be searched via the Proquest database.

Additional grey literature will be sourced through relevant websites such as the European Academy of Dental Sleep Medicine (EADSM; https://www.eadsm.eu/) and the American Academy of Dental Sleep Medicine (AADSM; http://www.aadsm.org/). The following organisations have been identified as being particularly relevant and their conference proceedings will be hand searched if not indexed in the bibliographic databases: American Academy of Orofacial Pain, European Academy of Craniomandibular Disorders, International Association for Study of Pain, International Association of Dental Research.

Data collection and analysis

Selection of studies

Two review authors will independently assess the abstracts of retrieved studies. We will obtain full text copies of studies deemed to be relevant, potentially relevant or for which there is insufficient information in the title and abstract to make a clear decision. Two review authors will independently assess the full text papers and any disagreements on the eligibility of studies will be resolved through discussion and consensus. If necessary, a third review author will be consulted.

Data extraction and management

The following data will be extracted from the included trials:

- Location/setting, type of provider, number of centres, recruitment period, trials registry ID.
- Inclusion/exclusion criteria, age and sex of participants, number randomised/analysed, any other important prognostic factors (i.e. co-morbidities, concomitant prescription medicines/co-interventions).
- Population characteristics: age, gender, presenting condition (bruxism,TMD [plus sub-type] or mixed) and severity, duration since presenting condition began, co-morbidities
- Intervention: primary purpose of splint (e.g. pain reduction, bruxist motor activity reduction, aid functional rehabilitation, decrease in tooth damage, jaw repositioning); type of splint in terms of jaw worn in (upper/lower), material (hard/soft/composite), teeth coverage (full/partial), design (prefabricated/custom made); duration of splint use
- Detailed description of comparator

- Details of the outcomes reported, including method of assessment and time(s) assessed.
- Details of sample size calculations, funding sources, declarations/conflicts of interest.

Assessment of risk of bias in included studies

The assessment of risk of bias will be done using the Cochrane risk of bias tool (Higgins 2011). The following domains will be assessed: sequence generation (selection bias); allocation concealment (selection bias); blinding of participants and personnel (performance bias); blinding of outcome assessors (detection bias); incomplete outcome data (attrition bias); selective outcome reporting (reporting bias); other bias. We realize that it will be difficult or impossible to blind the patients and personnel to whether or not the patient has been randomised to receiving a splint or not. This could potentially introduce performance bias, and, in the case of subjective outcomes, detection bias.

The overall risk of bias of individual studies will be categorised as being at: low, high or unclear risk of bias according to the following: low risk of bias (plausible bias unlikely to seriously alter the results) if all domains were at low risk of bias; unclear risk of bias (plausible bias that raises some doubt about the results) if one or more domains had an unclear risk of bias; or high risk if one or more domains had a high risk of bias.

Measures of treatment effect

For continuous outcomes (e.g. pain on a visual analogue scale), we will use the means and standard deviations reported in the trials in order to express the estimate of effect as mean difference with 95% confidence interval. In the event that different scales are used, we will consider expressing the treatment effect as standardised mean difference.

For dichotomous outcomes (e.g. jaw clicking/no jaw clicking), we will express the estimate of effect as a risk ratio with 95% confidence interval.

Unit of analysis issues

The patient will be the unit of analysis for all included studies

Dealing with missing data

We will attempt to contact the author(s) of all included studies, where feasible, for clarifications or missing data. Missing standard deviations will be estimated according to the methods described in section 7.7.3 of the Cochrane Handbook for Systematic Reviews of Interventions to estimate missing standard deviations (Higgins 2011).

Assessment of heterogeneity

If a sufficient number of studies are included in any meta-analyses, we will assess any clinical heterogeneity by examining the following characteristics of the studies: the similarity between the types of participants (TMD, bruxism: age (under 18 and 18+)), the type of healthcare worker providing the splints, the type of splint, the control intervention, and the outcomes.

We will also assess heterogeneity statistically by using a Chi^2 test, where a P value of less than 0.1 indicates statistically significant heterogeneity. We will quantify heterogeneity by using the I^2 statistic. A guide to the interpretation of the I^2 statistic, as given in the Cochrane Handbook (Higgins 2011), is as follows:

- 0% to 40%: might not be important;
- 30% to 60%: may represent moderate heterogeneity;
- 50% to 90%: may represent substantial heterogeneity;
- 75% to 100%: considerable heterogeneity.

Assessment of reporting biases

If a sufficient number of studies are included in any meta-analyses, publication bias will be assessed according to the recommendations on testing for funnel plot asymmetry (Egger 1997) as described in section 10.4.3.1 of the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011). If asymmetry is identified, other possible causes will be assessed.

Data synthesis

We will only carry out meta-analyses where there are studies of similar comparisons reporting the same outcomes. We will combine mean differences (or standardised mean differences where different scales were used) for continuous data, and risk ratios for dichotomous data. Our general approach will be to use a random-

effects model. With this approach, the confidence intervals for the average intervention effect will be wider than those that would have been obtained using a fixed-effect approach, leading to a more conservative interpretation.

We will use an additional table to report the results from studies not suitable for meta-analysis.

For the meta-analysis of splints versus no splints we will include prefabricated and custom-made splints as subgroups. Pooling across subgroups will depend on the degree of heterogeneity/subgroup differences. As an additional analysis, if we determine that there is evidence that the pre-fabricated splits when placed by any healthcare professional are effective for the primary outcomes, then we will look at any head to head RCTs comparing the delivery of pre-fabricated splints by different types of healthcare workers.

If appropriate we will consider undertaking a network meta-analysis for different splint types

Subgroup analysis and investigation of heterogeneity

For the meta-analysis of splints versus no splints we will include the following sub-groups:

- prefabricated
- hard custom made splints that alter occlusion (jaw relationship)
- hard custom made splints that do not alter occlusion (jaw relationship)
- soft custom made splints that do not alter occlusion (jaw relationship)

Sensitivity analysis

For TMD patients, we will undertake a sensitivity analysis restricted to trials where the inclusion criteria are based on, or can be clearly mapped to, one of the following sets of diagnostic criteria:

- Research Diagnostic Criteria for Temporomandibular disorders (RDC/TMD) guidelines (Dworkin 1992);
- TMD (DC/TMD) guidelines (Schiffman 2014);
- American Association of Orofacial Pain (AAOP) guidelines (De Leeuw 2013),

Similarly for bruxism patients sensitivity analysis will be undertaken restricting to trials where there is a clear diagnosis of bruxism (Lobbezoo 2013).

We will test the robustness of our results by performing sensitivity analyses based on excluding studies at high and unclear risk of bias from the analyses. It is unlikely to be possible to do this for the splint versus no splint comparison, if we judge that there is a high risk of performance bias or detection bias or both.

If any meta-analyses include several small studies and a single very large study, we will undertake sensitivity analyses comparing the effect estimates from both random-effects and fixed-effect models. If these are different, we will report on both analyses as part of the results section, and we will consider possible interpretation.

Presentation of main results

We aim to develop a summary of findings table for each comparison and for the main outcomes of this review following GRADE methods (GRADE 2004), and using the GRADEPro online tool (www.guidelinedevelopment.org). The quality of the body of evidence will be assessed with reference to the overall risk of bias of the included studies, the directness of the evidence, the inconsistency of the results, the precision of the estimates, and the risk of publication bias. We will categorise the quality of the body of evidence for each of the main outcomes for each comparison as high, moderate, low or very low.

Economics

Review of economic evaluation studies:

Whilst we don t expect to find any literature on the cost-effectiveness of oral splints, we will nonetheless conduct a review of the literature searching for any existing economic evaluations comparing (a) all oral splints versus no splints and b) prefabricated splints versus custom made splints provided by dentists for patients with orofacial signs or symptoms in accordance with the comparisons detailed in Section 4.1 above. Additional literature searching filters for economic evaluation studies will be used. A health economist will assess the title and abstract of all citations identified. Full-text papers of potentially relevant studies will be retrieved and assessed for inclusion. Only full formal economic evaluations (i.e. cost-minimization, cost-effectiveness, cost-utility or cost-benefit analyses) meeting the inclusion criteria outlined above will be deemed suitable for inclusion. The quality of any included studies will be assessed by means of (i) the BMJ checklist for referees of economic analyses (Drummond 1996) for economic evaluations conducted alongside RCTs, and (ii) where appropriate using the criteria for the review of economic models set out by Philips and colleagues (Philips 2004). A narrative summary of the findings of any included economic evaluation studies will be presented, and will be grouped according to

the two main research questions for this review. Additional data will be retrieved, as appropriate, to inform key model parameters (e.g. transition probabilities, resource use data, costs attributable to model health states and utilities).

Development of a Health Economic Model

Current economic evidence is unlikely to be sufficient to answer the decision problem for this assessment. Therefore, a *de novo* decision analysis model will be developed to conduct a full health economic evaluation, in the form of a cost utility analysis. The model will likely be a Markov cohort state transition model. The exact format and structure of the model will be decided in conjunction with dental experts on our advisory group and will be tailored depending on the availability of data from the systematic review and other supplementary reviews to populate model parameters.

The model will begin with patients presenting in primary dental care with the diagnostic criteria that would indicate a need for oral splints. Should sufficient evidence exist from the systematic review of RCTs to indicate a role for other health professionals in the provision of pre-fabricated splints, this will be considered as a sensitivity analysis in the model. The model will then describe the sequence of events (health states) experienced by these patients over time, including recurrent or unresolved symptoms, progression of existing symptoms (e.g. development of orofacial pain) and requirement for more dental or non-dental treatment. The model will consider the need for re-treatment (e.g. replacing soft splints with hard splints) as well as referral of patients for management in secondary care services (dental and non-dental as appropriate) for any reconstructive procedures (e.g. bridges etc.). The base case model time horizon will be determined by the accuracy of available evidence to enable longer term extrapolation. A life-time horizon will also be explored.
Costs and QALYs will be discounted at a rate of 3.5% per annum (NICE 2013).

The model will be populated as follows. Baseline transition probabilities will come from cohort data where applicable, including for example the DEEP study if appropriate (Durham 2016). Where such data are not available for baseline transition probabilities, data from the control arms of included RCTs will be used instead.

Relative risks will be applied to transition probabilities between health states based on the systematic review and the results of the meta-analysis (e.g. risk of orofacial pain). Supplementary assumptions may be required for the relative risk of progression between health states and where such assumptions are required, these will be informed by discussion with clinical experts and comprehensive sensitivity analyses will be carried out.

Costs will be assessed from an NHS perspective for the primary economic analysis. Given the co-payment structure for dental care in the UK, costs will also be assessed from a patient perspective. Resource use and costs (to the NHS and patient) for initial treatment provision will be based on the appropriate treatment band in England. Item for service fees from Scotland will also be included. Resources required for the treatment of bruxism or TMD related events will be sourced from the literature, including for example the DEEP study (Durham 2016) where appropriate. Where required, clinical expert opinions will be used to supplement missing information on resource use. Unit costs of dental treatments will be obtained from national sources, including banded treatments in England and ISD unit costs in Scotland. Any secondary care, hospital resource use will be costed using NHS reference costs. The resource use and cost data will be chosen which are most relevant to the UK care pathways.

Utility data will sourced from the systematic review and supplementary literature searches designed to obtain utility weights for orofacial symptoms. For example, the DEEP study provides EQ-5D weights for some orofacial symptoms (Durham 2016). Quality of life data, will be based on reported EQ-5D data where possible.
It is unlikely that a mortality effect will be observed in this study. Therefore, quality of life (utility) data will be combined with mortality data (from general population life tables) to estimate Quality Adjusted Life Years (QALYs).

Uncertainty surrounding point estimates of all model parameters (baseline transition probabilities, relative risks, costs and utilities) will be incorporated in the model through appropriately selected distributions (e.g. beta distributions for utility data). Methodological (e.g. discount rates / time horizon) and structural (e.g. most appropriate care pathways) uncertainty will be explored through comprehensive deterministic sensitivity analyses. Where appropriate scenario and threshold analyses will be used to illustrate the parameter values that would be required to change cost-effectiveness conclusions.

Following the primary objectives of the project, the economic results will be presented comparing (a) all oral splints versus no splints and b) prefabricated splints versus custom made splints provided by dentists for patients with orofacial signs or symptoms. Where possible, cost-effectiveness results will be presented separately for TMD and bruxism.

The model will report results primarily as incremental discounted costs, incremental discounted QALYs and incremental cost-effectiveness ratios. Scatter plots of simulated incremental costs and QALYs will be presented on the cost effectiveness plane and cost-effectiveness acceptability curves will be used to illustrate the probability of each strategy being cost-effective at alternative thresholds of society s willingness to pay for a QALY gained. A secondary economic analysis will report the results using an appropriate measure to match the primary clinical-effectiveness outcome (e.g. additional cost per case of orofacial pain avoided). We anticipate that there will be limited data available to determine longer term outcomes to populate the economic model. We will therefore also undertake a value of information analysis to determine the value of future research to resolve residual uncertainty surrounding estimates of cost-effectiveness. Expected value of perfect information (EVPI) and expected value of partial perfect information (EVPPI) will be reported to determine the value of targeted research to resolve uncertainty surrounding parameters that are the main drivers of cost-effectiveness in the model. EVPI and EVPPI analyses will help to prioritize future research needs regarding cost-effectiveness.

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Appendices

1 HTA 16/146 Oral splints for orofacial symptoms

Introduction
The aim of the HTA Programme is to ensure that high quality research information on the effectiveness, costs and broader impact of health technology is produced in the most efficient way for those who use, manage, provide care in or develop policy for the NHS. Topics for research are identified and prioritised to meet the needs of the NHS. Health technology assessment forms a substantial portfolio of work within the National Institute for Health Research and each year about fifty new studies are commissioned to help answer questions of direct importance to the NHS. The studies include both primary research and evidence synthesis.

Research Question:
What is the clinical and cost-effectiveness of prefabricated oral splints and custom-made splints for the treatment of orofacial symptoms?

1. Intervention: Prefabricated oral splints.
2. Patient group: Patients with orofacial symptoms, including pain, where oral splints are being considered.
3. Setting: Any setting where patients are seen by dentists.
4. Control: Custom-made splints, no splints.
5. Study design: An evidence synthesis by systematic review of the best available evidence and a model of cost-effectiveness.
6. Important outcomes: Changes in pain intensity and/or other symptoms. Overall dental health.
Other outcomes: Health-related quality of life; cost-effectiveness; acceptability and adherence.
Important outputs: Prioritised recommendations for future research, particularly consideration of whether trials are needed of (a) splints against no-splints or (b) between categories of splints.

NHS decision problem to be addressed by this research:

Orofacial symptoms are a common condition that may be caused or aggravated by bruxism (teeth clenching and grinding). Oral splints are frequently prescribed to reduce jaw muscle activity in order to reduce pain, and also to increase awareness of parafunctional habits, and to protect the teeth.

The splints can be prescribed within the General Dental Service and will usually be custom made in dental laboratories, using imprints taken from the patient's teeth. These splints are expensive to the NHS because they are time consuming in terms of both clinician and laboratory time. The intervention will incur a band 3 charge to the patient under the current NHS dental fee scale (currently around £220), but the patient charge would only cover about half of the full cost of laboratory made splints.

There is doubt about the benefits of splints. It has also been suggested that prefabricated oral splints may be a viable alternative to custom-made splints at a much lower cost to both patients and the NHS. Only one visit may be required for fitting a prefabricated splint as opposed to 2 visits required for imprints and fitting if laboratory-made splints were used.

There is some supportive evidence from primary research, but an evidence synthesis is needed to assess the clinical and cost effectiveness of prefabricated splints for the treatment of orofacial symptoms and to inform the need for future trials of these treatments.

2 MEDLINE Ovid search strategy

1. Occlusal adjustment/
2. Occlusal splints/
3. Orthodontic appliances/
4. ((occlusal or oral or temporomandibular or jaw$ or mandib$ or mouth$ or bite$ or TMJ or dental) adj5 splint$).mp.
5. ((dental or mouth or gum) adj (guard$ or shield$)).mp.
6. (mouthguard$ or gumguard$ or nightguard$ or gumshield$ or "bite plane$" or toothprotector$ or "tooth protector$").mp.
7. "splint therapy".mp.
8. ((oral or TMJ or orofacial) adj appliance$).mp.
9. or/1-8
10. exp Craniomandibular disorders/
11. Facial pain/
12. Facial neuralgia/
13. Trigeminal neuralgia/
14. Arthralgia/ and temporomandibular joint/
15. exp bruxism/
16. (bruxism or (teeth adj5 grind$) or (teeth adj5 clench) or (jaw$ adj5 clench) or (jaw$ adj5 grind$)).mp.
17. ((craniofacial or myofacial or myofascial or facial or orofacial) adj5 (pain$ or syndrome$)).mp.
18. ("trigeminal neuralgia" or "sphenopalatine neuralgia" or "Costen$ syndrome$").mp.
19. (("temporomandibular joint" or craniomandibular or jaw$ or mandib$) adj5 (pain$ or disorder$ or dysfunction$ or arthralgia or syndrome$)).mp.
20. (TMD or TMJD or (TMJ adj3 (disorder$ or dysfunction$ or syndrome$ or pain$))).ti,ab.
21. ((temporomandibular or jaw$ or mandib$) adj5 (disk or disc) adj displac$).mp.
22. or/10-21
23. 9 and 22

The above search will be linked to the Cochrane Highliy Sensitive Search Strategy for identifying randomized trials in MEDLINE: sensitivity- maximising version (2008 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] (Lefebvre 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