Health Technology Assessment Programme

National Institute for Health Research

HTA no 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.

Making an application

The NIHR Health Technology Assessment Programme is funded by the NIHR, with contributions from the CSO in Scotland, NISCHR in Wales, and the Public Health Agency in Northern Ireland.

If you wish to submit a proposal on this topic, complete the on-line application form at www.nets.nihr.ac.uk/funding/hta-commissioned and submit it on line by **9th February 2017.**

Your full proposal will be assessed by designated board members, alongside other applications submitted in the same topic area. A maximum of three proposals will be taken forward for peer review by external referees, and subsequent consideration by the HTA Funding Board at its meeting in **March 2017.**

In line with the government's transparency agenda, any contract resulting from this tender may be published in its entirety to the general public. Further information on the transparency agenda is at: http://transparency.number10.gov.uk/#

Applicants are recommended to seek advice from suitable methodological support services, at an appropriate stage in the development of their research idea and application. It is advisable to make contact at an early a stage as possible to allow sufficient time for discussion and a considered response.

The NIHR Research Design Service (http://www.rds.nihr.ac.uk/) can advise on appropriate NIHR Programme choice, and developing and designing high quality research grant applications.

Clinical Trials Toolkit

Researchers designing or undertaking clinical trials are encouraged to consult the Clinical Trials Toolkit (www.ct-toolkit.ac.uk). This NIHR resource is a website designed to help researchers navigate through the complex landscape of setting up and managing clinical trials in line with regulatory requirements. Although primarily aimed at those involved in publicly funded Clinical Trials of Investigational Medicinal Products (CTIMPs), the Toolkit will also benefit researchers and R&D staff

working on trials in other areas, who will find useful information and guidance of relevance to the wider trials environment.

Applications received electronically after 1300 hours on the due date will not be considered.

Please see GUIDANCE ON APPLICATIONS overleaf.

Should you have any queries please contact htagb@soton.ac.uk

Guidance on applications

Methods

Applicants should demonstrate knowledge of current research in the field and of systematic review methods and state how these would apply to the question posed. Valid and reliable methods should be proposed for identifying and selecting relevant material, assessing its quality and synthesising the results. Guidance on choice of appropriate methods is contained in NHS CRD Report *Systematic Reviews: CRD's guidance for undertaking reviews in health care (third edition)* (www.york.ac.uk/inst/crd/index_guidance.htm). Where established Core Outcomes exist they should be included amongst the list of outcomes unless there is good reason to do otherwise. Please see The COMET Initiative website at www.comet-initiative.org to identify whether Core Outcomes have been established. Where policy implications are considered, the emphasis should be on assessing the likely effects of a range of policy options open to decision makers rather than a judgement on any single strategy. Where epidemiological modelling or economic evaluation is required, the range of uncertainty associated with the results should be assessed. In the assessment of cost-effectiveness, further data collection may be required to estimate resource use and costs. If there is evidence that the ratio of costs and benefits may differ between readily identifiable groups, applicants are encouraged to state how they will identify these differences. Where relevant, researchers should explore the effect of the intervention in relation to health inequalities.

Cochrane

Applicants wishing to produce and maintain a Cochrane systematic review from a HTA commissioned systematic review should make the case in their proposal. This will need to include the approval of the relevant Cochrane Review Group (www.cochrane.org). Any additional costs associated with the initial preparation of a Cochrane review should be included in your project proposal. Maintenance costs cannot be met.

Diagnostics and Imaging

In evaluating diagnostic and imaging techniques, the emphasis of the HTA Programme is to assess

the effect on patient management and outcomes (particularly where changes in management can be shown to have patient benefits). Improvements in diagnostic accuracy, whilst relevant, are not the primary interest of this commissioned research programme. Applicants should justify where they consider improvements in diagnostic accuracy to be relevant to these objectives. Where there is poor evidence to link diagnostic improvements to patient benefits, part of the research may be to assess the effects of such changes on patient outcome.

Public involvement in research

The HTA Programme recognises the benefit of increasing active involvement of members of the public in research and would like to support research projects appropriately. The HTA Programme encourages applicants to consider *how* the scientific quality, feasibility or practicality of their proposal *could* be improved by involving members of the public. Examples of how this has been done for health technology assessment projects can be found at www.nets.nihr.ac.uk/ppi. Research teams wishing to involve members of the public should include in their application: the aims of active involvement in this project; a description of the members of the public (to be) involved; a description of the methods of involvement; and an appropriate budget. Applications that involve members of the public will not, for that reason alone, be favoured over proposals that do not but it is hoped that the involvement of members of the public will improve the quality of the application.

Updating

It is the policy of NETSCC, HTA that all search strategies undertaken as part of evidence synthesis/secondary research projects must not be more than 12 months out of date when the draft final report is submitted. We expect that most projects will manage to bring their searches up to date prior to analysis and writing up. As research funders we are aware that exceptional circumstances can apply that would not allow this to be case but this must be the exception rather than the rule and will be assessed on a case by case basis. The expectation is that projects funded by the HTA Programme will deliver information that is both relevant and timely.

In addition, in order to inform decisions on whether and when to update the review, researchers will be expected to give some indication of how fast the evidence base is changing in the field concerned, based on the nature and volume of on-going work known at the time the review is completed. Applicants should note that they will not be expected to carry out any future updating as part of the contract to complete the review.

Communication

Communication of the results of research to decision makers in the NHS is central to the HTA Programme. Successful applicants will be required to submit a single final report for publication by the HTA Programme. They are also required to communicate their work through peer-reviewed journals and may also be asked to support NETSCC, HTA in further efforts to ensure that results are readily available to all relevant parties in the NHS. Where findings demonstrate continuing uncertainty, these should be highlighted as areas for further research.

Timescale

There are no fixed limits on the duration of projects or funding. However, there is a pressing need within the NHS for the information and so the research would normally be expected to be completed as soon as possible – however it is for applicants to justify the duration and costs proposed.