Clinical effectiveness and cost-effectiveness results from the randomised controlled Trial of Oral Mandibular Advancement Devices for Obstructive sleep apnoea–hypopnoea (TOMADO) and long-term economic analysis of oral devices and continuous positive airway pressure

Linda Sharples,[1,2,3] Matthew Glover,[4] Abigail Clutterbuck-James,[3] Maxine Bennett,[2] Jake Jordan,[4] Rebecca Chadwick,[3] Marcus Pittman,[3] Clare East,[3] Malcolm Cameron,[5] Mike Davies,[3] Nick Oscroft,[3] Ian Smith,[3] Mary Morrell,[6] Julia Fox-Rushby[4] and Timothy Quinnell[3]*

[1]University of Leeds Clinical Trials Research Unit, Leeds, UK
[2]Medical Research Council Biostatistics Unit, Cambridge, UK
[3]Papworth Hospital NHS Foundation Trust, Papworth Everard, Cambridge, UK
[4]Health Economics Research Unit, Brunel University, Uxbridge, UK
[5]Maxillofacial Unit, Addenbrooke's NHS Foundation Trust, Cambridge, UK
[6]National Heart and Lung Institute, Imperial College London, London, UK

*Corresponding author

Declared competing interests of authors: Malcolm Cameron provides the bespoke device service at Addenbrooke's Hospital. Timothy Quinnell received personal fees from UCB Pharma (who have no commercial interest in this study area) for attending the European Sleep Research Society Conference in September 2012. There are no other conflicts of interest to declare.

Published October 2014
DOI: 10.3310/hta18670

Plain English summary

Effectiveness results from TOMADO and analysis of oral devices and CPAP

Health Technology Assessment 2014; Vol. 18: No. 67
DOI: 10.3310/hta18670

NIHR Journals Library www.journalslibrary.nihr.ac.uk

Plain English summary

In obstructive sleep apnoea–hypopnoea (OSAH), the airways become blocked during sleep. Breathing becomes shallow or stops, waking the patient suddenly. OSAH causes daytime sleepiness which affects working, driving and other activities, as well as quality of life. It causes hypertension, which is associated with heart disease and strokes. In severe OSAH, the airways are kept open using continuous positive airway pressure (CPAP). This reduces breathing irregularity and daytime sleepiness but requires the patient to wear a mask overnight and is intrusive. An alternative is a mandibular advancement device (MAD) that fits in the mouth like a gum shield. This is less clinically effective at reducing breathing irregularity, but similarly clinically effective at controlling daytime sleepiness, and may be better for mild disease.

We conducted a randomised controlled trial [the Trial of Oral Mandibular Advancement Devices for Obstructive sleep apnoea–hypopnoea (TOMADO)] comparing three MADs (bespoke, semibespoke and over the counter) with no treatment in patients with mild OSAH. All three MADs were significantly better than no treatment in reducing breathing disruption and daytime sleepiness, and the differences between MADs were small. The semi-bespoke MAD was most cost-effective in the short-term.

This trial was combined with relevant published trials of MADs and CPAP, and longer-term evidence on heart disease, stroke and road traffic accidents. This showed that:

- CPAP is the most effective treatment in moderate to severe OSAH based on reduction in apnoea–hypopnoea index.
- MADs and CPAP are equally effective treatment options for mild to moderate OSAH based on health outcomes and cost, but this is contingent on good compliance with treatment.
- Of the MADs investigated, the semi-bespoke device should be the first choice.

Health Technology Assessment

HTA/HTA TAR

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 5.116

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, The Cochrane Library and the ISI Science Citation Index and is assessed for inclusion in the Database of Abstracts of Reviews of Effects.

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: nihredit@southampton.ac.uk

The full HTA archive is freely available to view online at www.journalslibrary.nihr.ac.uk/hta. Print-on-demand copies can be purchased from the report pages of the NIHR Journals Library website: www.journalslibrary.nihr.ac.uk

Criteria for inclusion in the *Health Technology Assessment* journal

Reports are published in *Health Technology Assessment* (HTA) if (1) they have resulted from work for the HTA programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

HTA programme

The HTA programme, part of the National Institute for Health Research (NIHR), was set up in 1993. It produces high-quality research information on the effectiveness, costs and broader impact of health technologies for those who use, manage and provide care in the NHS. 'Health technologies' are broadly defined as all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care.

The journal is indexed in NHS Evidence via its abstracts included in MEDLINE and its Technology Assessment Reports inform National Institute for Health and Care Excellence (NICE) guidance. HTA research is also an important source of evidence for National Screening Committee (NSC) policy decisions.

For more information about the HTA programme please visit the website: http://www.nets.nihr.ac.uk/programmes/hta

This report

The research reported in this issue of the journal was funded by the HTA programme as project number 08/110/03. The contractual start date was in September 2010. The draft report began editorial review in January 2014 and was accepted for publication in April 2014. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Prepress Projects Ltd, Perth, Scotland (www.prepress-projects.co.uk).