

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-Rushby⁴ and Timothy Quinnell^{3*}

¹University of Leeds Clinical Trials Research Unit, Leeds, UK

²Medical Research Council Biostatistics Unit, Cambridge, UK

³Papworth Hospital NHS Foundation Trust, Papworth Everard, Cambridge, UK

⁴Health Economics Research Unit, Brunel University, Uxbridge, UK

⁵Maxillofacial Unit, Addenbrooke's NHS Foundation Trust, Cambridge, UK

⁶National 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.

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.

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Editorial contact: nihredit@southampton.ac.uk

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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.

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