

# Daytime intraoral neuromuscular electrical tongue stimulation using a removable device for obstructive sleep apnoea

Interventional procedures guidance  
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[www.nice.org.uk/guidance/ipg760](https://www.nice.org.uk/guidance/ipg760)

## Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment

or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should [assess and reduce the environmental impact of implementing NICE recommendations](#) wherever possible.

# 1 Recommendations

- 1.1 Evidence on the safety and efficacy of daytime intraoral neuromuscular electrical tongue stimulation using a removable device for obstructive sleep apnoea is inadequate in quality and quantity. So, this procedure should be used only in research. Find out [what only in research means on the NICE interventional procedures guidance page](#).
- 1.2 Further research should include suitably powered randomised controlled trials and analysis of observational data, to assess efficacy, safety and adherence. Research should report details of patient selection, duration of treatment and effect, effect on snoring and sleep apnoea, quality of life and complications.

# 2 The condition, current treatments and procedure

## The condition

- 2.1 Obstructive sleep apnoea (OSA) is a condition in which the upper airway narrows or closes during sleep when the throat muscles intermittently

relax. This causes reduced breathing (hypopnoea) or breathing to temporarily stop (apnoea). OSA can lead to major neurocognitive and cardiovascular sequelae.

## Current treatments

- 2.2 Management of OSA includes lifestyle changes (such as weight loss), continuous positive airway pressure, oral devices (mandibular advancement devices), neuromuscular electrical stimulation and upper airway surgery.

## The procedure

- 2.3 In this procedure, an intraoral removable device is used to deliver neuromuscular electrical stimulation to the intrinsic and extrinsic (genioglossus) muscles of the tongue. The aim is to improve tongue endurance and reduce airway obstruction during sleep.
- 2.4 A mouthpiece with an electrode array that fits onto the tongue is placed in the mouth by the person during the daytime while they are awake. Bipolar biphasic current is then delivered for about 20 minutes with predetermined low frequency stimulation and rest periods. The mouthpiece is removed once the session is complete. The intensity of the stimulation is controlled by the person, for example by using a smartphone app. An entire therapy usually lasts about 6 weeks, with a 20-minute daytime session each day while awake.

## 3 Committee considerations

### The evidence

- 3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 2 sources, which was discussed by the committee. The evidence included 1 single-arm clinical trial (3 papers) and 1 pilot study. It is presented in the [summary of key](#)

[evidence section in the interventional procedures overview](#). Other relevant literature is in the appendix of the overview. The committee also considered additional confidential documentation provided by a company.

- 3.2 The professional experts and the committee considered the key efficacy outcomes to be: adherence, improvement in sleep apnoea, reduction in snoring and improvement in quality of life (of the person with obstructive sleep apnoea and their bed partner).
- 3.3 The professional experts and the committee considered the key safety outcomes to be: pain and tingling or unpleasant sensation in the mouth.
- 3.4 Two submissions from patient organisations about this procedure were discussed by the committee. Patient commentary was sought but none was received.

## Committee comments

- 3.5 The committee noted that this procedure is currently only indicated for mild obstructive sleep apnoea.

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## Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).

## Accreditation

