

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Transcutaneous electrical stimulation of the trigeminal nerve for ADHD

Attention deficit hyperactivity disorder (ADHD) can cause restlessness, hyperactivity and difficulty focusing on tasks. In this procedure, which is done at home, a single-use electrode patch is stuck to the forehead at bedtime. Wires connect the patch to a stimulator that sends small electrical pulses through the skin (transcutaneous) during sleep. The pulses stimulate the trigeminal nerve, which connects to parts of the brain that are thought to control attention. Treatment usually lasts for about 4 weeks. The aim is to reduce ADHD symptoms.

NICE is looking at transcutaneous electrical stimulation of the trigeminal nerve for ADHD.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts with knowledge of the procedure.

This document contains the [draft guidance for consultation](#). Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance
- prepare a second draft, which will go through a [resolution process](#) before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 18 August 2022

Target date for publication of guidance: December 2022

1 Draft recommendations

- 1.1 Evidence on the safety and efficacy of transcutaneous electrical stimulation of the trigeminal nerve for attention deficit hyperactivity disorder (ADHD) is inadequate in quality and quantity. Therefore, this procedure should only be used in the context of research. Find out [what only in research means on the NICE interventional procedures guidance page](#).
- 1.2 Further research should be in the form of randomised controlled trials and should include details of patient selection, treatment protocols, adherence and long-term outcomes.

2 The condition, current treatments and procedure

The condition

- 2.1 Attention deficit hyperactivity disorder (ADHD) is a heterogeneous disorder characterised by the core symptoms of hyperactivity, impulsivity and inattention, which are judged excessive for the person's age or level of overall development. Symptoms are usually evident in childhood and may persist into adulthood.

Current treatments

- 2.2 Treatment for ADHD may be non-pharmacological, pharmacological, or a combination of both. Non-pharmacological treatment includes cognitive behavioural therapy and parent-training programmes (for parents of children and young people with ADHD). Pharmacological treatment includes central nervous system stimulants such as methylphenidate and amphetamines.

The procedure

- 2.3 In this procedure, an external trigeminal nerve stimulation device is worn on the clothes and attached by wires to a single-use adhesive

patch which is worn overnight. The patch contains 2 electrodes placed over the left and right V1 branches of the trigeminal nerve on the forehead. The stimulator bilaterally stimulates the trigeminal nerve for approximately 8 hours. For children, parents or carers attach the device. In a typical treatment course, stimulation is given nightly for approximately 4 weeks. Treatment duration may vary – a clinical response may take longer, and continued therapy may be needed.

- 2.4 The mechanism of action is not completely understood. The trigeminal nerve connects to regions of the brain that may be associated with selective maintenance of attention, and it is thought that its stimulation improves the symptoms of ADHD.

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 3 sources, which was discussed by the committee. The evidence included 1 randomised controlled trial (with 1 secondary analysis) and 1 open-label trial. It is presented in the [summary of key evidence section in the interventional procedures overview](#).
- 3.2 The professional experts and the committee considered the key efficacy outcomes to be: improved quality of life, reduced symptoms and reduced need for medication.
- 3.3 The professional experts and the committee considered the key safety outcomes to be: pain, skin irritation, negative effect on cognitive function and worsening of symptoms.
- 3.4 Patient commentary was sought but none was received.

Committee comments

- 3.5 The committee was informed that the procedure is primarily indicated for people for whom medication is unsuitable.
- 3.6 The device has regulatory approval for use in people aged 7 and over, but all the evidence that the committee considered was from children.
- 3.7 The committee was informed that treatment usually takes place at night and that a course of treatment may need to be repeated.

Tom Clutton-Brock

Chair, interventional procedures advisory committee

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