# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Interventional procedures consultation document

# Transcutaneous electrical neuromuscular stimulation for urinary incontinence

Urinary incontinence is when people have problems controlling their bladder. They may have a sudden need to urinate that leads to leaks (urge incontinence) or urine may leak with exercise, coughing, laughing or sneezing (stress incontinence). It's possible to have both stress and urge urinary incontinence together. This procedure uses external electrodes placed on to the skin (transcutaneous), to stimulate nerves and muscles (neuromuscular) in the pelvic floor. The aim is to strengthen the pelvic floor and reduce leaks.

NICE is looking at transcutaneous electrical neuromuscular stimulation for urinary incontinence.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts, who are consultants 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This document contains the draft guidance for consultation.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 The draft guidance may change after this consultation.**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- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance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: 14 April 2022

Target date for publication of guidance: August 2022

# 1 Draft recommendations

1.1 Evidence on the safety of transcutaneous electrical neuromuscular stimulation for urinary incontinence raises no major safety concerns. Evidence on its efficacy is limited in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. Find out what special arrangements mean on the NICE interventional procedures guidance page.

1.2 Clinicians wanting to do transcutaneous electrical neuromuscular stimulation for urinary incontinence should:

- Inform the clinical governance leads in their healthcare organisation.
- Give people (and their families and carers as appropriate) clear written information to support shared decision making, including NICE's information for the public.
- Ensure that people (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
- Audit and review clinical outcomes of everyone having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into NICE's interventional procedure outcomes audit tool (for use at local discretion).
- Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.

1.3 Healthcare organisations should:

- Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for everyone having this procedure.
- Regularly review data on outcomes and safety for this procedure.

1.4 Further research should include randomised controlled trials comparing transcutaneous neuromuscular electrical stimulation plus pelvic floor muscle exercises with pelvic floor muscle exercises alone.

# 2 The condition, current treatments and procedure

## The condition

2.1 Stress urinary incontinence is the involuntary leakage of urine during exercise or certain movements such as coughing, sneezing and laughing. Urge urinary incontinence is involuntary urine leakage with a feeling of urgency (a sudden need to urinate that is difficult to delay) during or just before the leakage. Mixed urinary incontinence is involuntary urine leakage associated with both urgency and exercise, effort, sneezing or coughing.

## Current treatments

2.2 NICE's guideline on urinary incontinence and pelvic organ prolapse has recommendations for the management of urinary incontinence in women, with a patient decision aid to promote shared decision making. NICE's guideline on lower urinary tract symptoms in men has recommendations for the management of urinary incontinence in men. Conventional treatment is conservative and includes lifestyle changes such as weight loss and pelvic floor muscle training. Surgical options are only offered if conservative measures and drug treatments do not help.

## The procedure

2.3 The procedure uses non-implanted electrodes connected to an external neuromuscular electrical stimulator device to stimulate muscles and nerves, to make the pelvic floor muscles contract. The electrical stimulation is delivered through the skin, typically with

sticky pad electrodes. The number and placement of electrodes varies according to the system being used. This includes a design in which the electrodes are incorporated into a body garment worn like a pair of shorts. A controller is used to vary the intensity and frequency of stimulations, to achieve a lifting sensation throughout the pelvic floor.

2.4 The device is typically used in sessions. The number and frequency of advised sessions varies, but the treatment period is typically 6 to 12 weeks.

2.5 The aim of the procedure is to reduce symptoms associated with stress or urge urinary incontinence.

# 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 8 sources, which was discussed by the committee. The evidence included 6 randomised controlled trials, 1 non-randomised comparative study and 1 cohort 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.

3.2 The professional experts and the committee considered the key efficacy outcomes to be: improved quality of life, reduced stress incontinence, reduced pad use.

3.3 The professional experts and the committee considered the key safety outcomes to be: pain or discomfort, skin irritation or burns at electrode sites.

3.4 Patient commentary was sought but none was received.

## Committee comments

3.5 Most of the evidence was from studies of women with stress urinary incontinence, which is the primary indication for this procedure.

3.6 There are several devices available, but most of the evidence came from a single device.

3.7 The committee noted that transcutaneous electrical neuromuscular stimulation is an adjunct to pelvic floor muscle exercises.

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Chair, interventional procedures advisory committee
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