NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of 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.

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Abbreviations

Word or phrase	Abbreviation
Bristol Female Urinary Symptoms Questionnaire	BFUSQ
Confidence interval	CI
International Consultation on Incontinence Questionnaire-Short Form	ICIQ-SF
Incontinence Quality of Life	I-QoL
King's Health Questionnaire	KHQ
Neuromuscular electrical stimulation	NMES
Short Form Health Survey	SF-12
Standard deviation	SD
Standard error	SE
Stress urinary incontinence	SUI

Introduction

The National Institute for Health and Care Excellence (NICE) prepared this interventional procedure overview to help members of the interventional procedures advisory committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and professional opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in December 2021 and updated in June 2022.

Procedure name

- Transcutaneous electrical neuromuscular stimulation for urinary incontinence

Professional societies

- British Society of Urogynaecology

- British Association of Urological Surgeons
- Royal College of Obstetricians and Gynaecologists
- Pelvic, Obstetric and Gynaecological Physiotherapy.

Description of the procedure

Indications and current treatment

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 compelling desire 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. These symptoms may be present in women with or without prolapse.

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.

What the procedure involves

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.

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.

The aim of the procedure is to reduce symptoms associated with stress or urge urinary incontinence, as an adjunct to pelvic floor muscle exercises.

Outcome measures

King's Health Questionnaire (KHQ)

The KHQ is a validated instrument for measuring the quality of life of women with urinary incontinence. It consists of 30 questions, divided into 9 individually scored domains. The total score ranges from 0 to 100: a score of 100 represents the worst possible quality of life, and 0 represents the best possible quality of life.

International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF)

The ICIQ Short Form is a questionnaire for evaluating the frequency, severity and impact on quality of life of urinary incontinence in men and women. It has 4 items (frequency of urinary incontinence, amount of leakage, overall impact of urinary incontinence, self-diagnostic item), with a total score ranging from 0 to 21. The score is divided into the following severity categories: slight (1 to 5), moderate (6 to 12), severe (13 to 18) and very severe (19 to 21).

Efficacy summary

Pad weight test

In a randomised controlled trial of 180 women with SUI, a 50% reduction in provocative pad weight at the end of treatment (week 12) was reported in 56% of those who had external NMES compared with 63% of those who had intravaginal electrical stimulation (difference -6.7%, 95% CI -21.7% to 8.4%; Dmochowski 2019). In a randomised controlled trial of 45 women with SUI, the mean 1-hour pad weight reduced from 6.28 g to 3.31 g (p=0.01) in those who had surface stimulation and from 2.20 g to 0.41 g (p=0.01) in those who had intravaginal stimulation. It increased from 7.33 g to 7.62 g (p=0.61) in the control group (no treatment). The difference between the groups at the end of treatment was statistically significant (p=0.0005; Correia 2014).

A randomised controlled trial was done of 48 women who had either NMES plus Kegel exercises or Kegel exercises only for 4 weeks after surgery for SUI. The mean 24-hour pad weight at the end of treatment (4 weeks) was 5.4 g in the external NMES plus Kegel exercises group and 7.4 g in the Kegel exercises alone group (p=0.169; Karaman 2020).

A randomised controlled trial was done of 70 men with SUI after radical prostatectomy who had electrical stimulation through surface electrodes or an intra-anal probe. The mean differences in 24-hour pad weight after 10 weeks of treatment were 231.9 g (90% CI 134.3 to 329.3; p<0.001) and 245.2 g (90% CI

149.6 to 340.7; p<0.001) respectively in the per protocol analysis. In the intent-to-treat analysis, the mean difference was 248.5 g (90% CI 148.3 to 348.8) in men who had surface electrodes and 235.8 g (90% CI 145.2 to 326.4) in men who had an intra-anal probe (Pane-Alemany 2021).

In a non-randomised comparative study of 163 women with urinary incontinence after a stroke (not further described), urine leakage assessed by a 1-hour pad test reduced by 10.9 ml in the NMES group and by 5.0 ml in the control group (p<0.01) after 8 weeks of treatment (Shen 2018).

Incontinence episodes

In the randomised controlled trial of 180 women with SUI, 71% of women who had external NMES reported improvement in symptoms at week 12 compared with 63% of those who had intravaginal electrical stimulation (p value not reported). The mean number of incontinence episodes per day reduced from 2.98 to 1.74 in the external NMES group and from 2.93 to 1.51 in the intravaginal group (difference 0.18, 95% CI -0.74 to 1.11; Dmochowski 2019).

In the randomised controlled trial of 48 women who had either NMES plus Kegel exercises or Kegel exercises only for 4 weeks after surgery for SUI, 10% (2/20) of those in the NMES group had recurrence of urinary incontinence compared with 18% (5/28) of those in the Kegel exercise only group (p=0.02). The mean number of urine leakages in 24 hours at the end of treatment (4 weeks) was 1.6 in the external NMES plus Kegel exercises group compared with 3.2 in the Kegel exercises alone group (p=0.03; Karaman 2020).

A randomised controlled trial was done of 66 women with overactive bladder and urgency urinary incontinence. The median number of incontinence episodes reduced from 0.3 to 0 (p=0.003) in those who had electrical stimulation, from 2.2 to 0 (p=0.001) in those who had Kinesio taping and from 2.3 to 1.0 (p=0.001) in the pelvic floor muscle exercise only group (p=0.01 between groups; Celenay 2021).

In a cohort study of 20 women with mild or moderate SUI, the mean number of leaks per day reduced from 1.84 before the treatment to 0.58 (p<0.0001) at the end of treatment (6 weeks; Kolb 2019).

Pad use

In the randomised controlled trial of 180 women with SUI, the mean number of pads used per day reduced from 2.05 to 1.75 in the external NMES group and from 1.96 to 1.52 in the intravaginal group (difference 0.14, 95% CI -0.15 to 0.44; Dmochowski 2019). In the cohort study of 20 people with mild or moderate SUI, the mean number of pads per day reduced from 1.8 to 0.8 (p<0.001; Kolb 2019).

Quality of life

In the randomised controlled trial of 180 women with SUI, the mean Incontinence Quality of life Questionnaire score improved by 13.4 points in the external NMES group at week 12 compared with 15.4 points in the intravaginal electrical stimulation group (difference -2.01, 95% CI -7.16 to 3.15; Dmochowski 2019).

In the randomised controlled trial of 45 women with SUI, the mean KHQ incontinence impact score reduced from 57.8 to 6.66 (p=0.0005) in those who had surface stimulation. It reduced from 64.4 to 4.44 (p=0.0005) in those who had intravaginal stimulation and increased from 58.3 to 61.1 (p=0.44) in the control group (no treatment). The difference between the groups at the end of treatment was statistically significant (p<0.0001; Correia 2014).

In the randomised controlled trial of 48 women who had had surgery for SUI, the mean quality-of-life score at the end of treatment (4 weeks) was 7.3 in the external NMES plus Kegel exercises group compared with 18.4 in the Kegel exercises alone group (p=0.01; Karaman 2020).

In the randomised controlled trial of 66 women with overactive bladder and urgency urinary incontinence, the median incontinence impact score on the KHQ improved from 100.0 to 33.3 (p=0.001) in those who had electrical stimulation. It improved from 83.3 to 33.3 (p=0.001) in those who had Kinesio taping and from 100.0 to 66.7 (p=0.022) in the pelvic floor muscle exercise only group (p=0.109 between groups; Celenay 2021).

In a randomised controlled trial of 82 people with urinary incontinence after stroke, the mean ICIQ-SF score after treatment was 7.8 in those who had external NMES compared with 10.5 in those who had a sham procedure (p<0.01; Guo 2018).

In the randomised controlled trial of 70 men with SUI after radical prostatectomy, the mean ICIQ-SF score improved by 3.8 points (90% CI 2.4 to 5.2; p<0.001) in the surface electrode group and 4.1 points (90% CI 2.8 to 5.5; p<0.001) in the intra-anal probe group (intent-to-treat analysis) after 10 weeks of treatment. The mean I-QOL score improved by 25.1 points (90% CI 18.7 to 31.4; p<0.001) in the surface electrode group and 21.1 points (90% CI 14.6 to 27.5; p<0.001) in the intra-anal probe group in the same study (Pane-Alemany 2021).

In the non-randomised comparative study of 163 women with urinary incontinence after a stroke, the ICIQ-SF score improved by 4.2 points in the NMES group and by 1.3 points in the control group (p<0.01) after 8 weeks of treatment (Shen 2018).

In the cohort study of 20 women with mild or moderate SUI, the mean I-QoL score improved from 70.3 at baseline to 84.8 ($p<0.0002$) at the end of treatment (Kolb 2019).

Patient satisfaction

In the cohort study of 20 women with mild or moderate SUI, 83% were satisfied with their treatment (Kolb 2019).

Urodynamic values

In the randomised controlled trial of 82 people with urinary incontinence after stroke, the mean change in maximum cystometric capacity after treatment was 105.3 ml in the external NMES group compared with 10.3 ml in the sham group ($p<0.01$). The mean change in detrusor pressure was -11.8 cmH_2O in the external NMES group compared with -10.2 cmH_2O in the sham group ($p<0.01$). The change in maximum flow rate was 8.9 ml/second compared with 0.4 ml/second ($p<0.01$; Guo 2018).

Pelvic floor muscle strength

In the randomised controlled trial of 66 women with overactive bladder and urgency urinary incontinence, the median pelvic floor muscle strength improved from 5.0 to 8.0 kPa ($p=0.001$) in those who had electrical stimulation and in those who had Kinesio taping. It improved from 4.5 to 7.3 kPa ($p=0.001$) in the pelvic floor muscle exercise only group ($p=0.209$ between groups; Celenay 2021).

In the randomised controlled trial of 45 women with SUI, the mean pelvic floor muscle strength improved from 2.06 to 2.53 ($p=0.07$) in those who had surface stimulation and from 2.00 to 2.66 ($p=0.007$) in those who had intravaginal stimulation. It improved from 2.16 to 2.25 ($p=0.99$) in the control group (no treatment). The difference between the groups at the end of treatment was not statistically significant ($p=0.29$). The mean pressure of the pelvic floor muscle contraction improved from 39.4 to 47.4 cmH_2O ($p=0.004$) in those who had surface stimulation, from 37.4 to 44.2 cmH_2O ($p=0.04$) in those who had intravaginal stimulation. It decreased from 37.9 to 37.7 cmH_2O ($p=0.58$) in the control group (no treatment). The difference between the groups was not statistically significant (Correia 2014).

Safety summary

Medical device discomfort or pain

Medical device discomfort was reported in 9% (8/89) of people who had external NMES and 1% (1/91) of people who had intravaginal electrical stimulation in the randomised controlled trial of 180 people. Medical device pain was reported in 5% (4/89) and 1% (1/91) of people, respectively (Dmochowski 2019).

Urinary disorders

Dysuria and micturition urgency were reported in 1 person each who had external NMES and in no people who had intravaginal electrical stimulation in the randomised controlled trial of 180 people (Dmochowski 2019).

Skin disorders

Erythema and rash were reported in 1 person each who had external NMES and pruritis was reported in 1 person who had intravaginal electrical stimulation in the randomised controlled trial of 180 people. Skin irritation was reported in 3% (3/89) of people who had external NMES and 1% (1/91) of people who had intravaginal electrical stimulation (Dmochowski 2019).

Musculoskeletal disorders

Arthralgia and myalgia were reported in 1 person each who had external NMES and in no people who had intravaginal electrical stimulation in the randomised controlled trial of 180 people (Dmochowski 2019).

Anecdotal and theoretical adverse events

In addition to safety outcomes reported in the literature, professional experts are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never happened).

For this procedure, professional experts did not describe any additional anecdotal or theoretical adverse events.

The evidence assessed

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to transcutaneous electrical neuromuscular stimulation for urinary incontinence. The following databases were searched, covering the period from their start to 8 April 2022: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see the literature search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The inclusion criteria were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Adults with urinary incontinence
Intervention/test	Transcutaneous electrical neuromuscular stimulation
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the IP overview

This IP overview is based on 674 people from 6 randomised controlled trials, 1 non-randomised comparative study and 1 cohort study (Dmochowski, 2019;

Celenay, 2021; Correia, 2014; Karaman, 2020; Guo, 2018; Pane-Alemany, 2021; Shen, 2018; Kolb, 2019).

Other studies that were considered to be relevant to the procedure but were not included in the main summary of the key evidence are listed in the appendix.

Summary of key evidence on transcutaneous electrical neuromuscular stimulation for urinary incontinence

Study 1 Dmochowski R (2019)

Study details

Study type	Randomised controlled trial
Country	US (12 centres)
Recruitment period	2015 to 2017
Study population and number	n=180 (89 external neuromuscular electrical stimulation [NMES], 91 intravaginal electrical stimulation) Women with SUI
Age and sex	Mean (years): 45.9 (external NMES), 47.8 (intravaginal electrical stimulation); 100% female
Patient selection criteria	Participants were women aged 18 to 65 years with a body mass index of 35 kg/m^2 or less and clinically diagnosed SUI that had not improved with formal pretrial Kegel exercises taught by a physical therapist. They had to score 9 out of 18 or less on the urge incontinence questions and have predominant SUI according to the Medical, Epidemiologic, and Social Aspects of Aging Urinary Incontinence Questionnaire at screening and have urine leakage of 3 to 90 g in a 1-hour provocative pad weight test at baseline. Other SUI treatments, including new pelvic floor muscle training exercises, were not allowed during the study. Main exclusion criteria: medical or physical conditions that could compromise participation (such as reduced sensory perception in electrode contact areas); bladder abnormalities affecting lower urinary tract urinary flow; other urogynaecological disorders or prior treatments that could affect outcomes; metal or conductive implants or devices or conditions that could be adversely affected by electrical stimulation.
Technique	NMES device: INNOVO (Atlantic Therapeutics, Galway, Ireland), formerly Vital Compact (Bio-Medical Research Ltd). Controller specifications include 50 Hz frequency, 620 µs pulse width, 0.5-second ramp-up and ramp-down times, 5-second contraction time, and 5-second relaxation time. Intravaginal device: iTouch sure (TensCare Ltd, UK). Controller specifications were: 50 Hz frequency, 300 µs pulse width, 1-second ramp-up and down, 5-second plateau, and 10-second rest. In both groups, treatment continued for 12 weeks and was self-administered at home after appropriate training in the clinic. Devices were used in accordance with the manufacturers' device instructions for use, including adjustment of stimulation intensity, treatment session frequency, and duration, and overall treatment period. The external NMES device was used for 30 minutes once daily for 5 days per week. The intravaginal device was used for 20 minutes once daily for 7 days per week.

Follow up	End of treatment (12 weeks)
Conflict of interest/source of funding	The study was funded by Atlantic Therapeutics Ltd. Two authors are Clinical Advisors to Atlantic Therapeutics Ltd.

Analysis

Follow-up issues: Patients were evaluated at study sites at screening, baseline, and at 4 and 12 weeks during the treatment period. The 12-week treatment period was completed by 89% of patients in the external NMES group and 88% in the comparator group. The most common reason for early withdrawal from the study was patient request (external NMES 7%, comparator 6%). Of the 180 patients, 4 were lost to follow up (1 in the external NMES group and 3 in the comparator group).

Study design issues: Prospective, multicentre, single-blind, non-inferiority randomised controlled trial. Treatment was assigned according to a randomisation schedule using a permuted block-format, stratified by study site. Designated unblinded study personnel trained patients in device use. Investigators and staff doing assessments were blinded to treatment assignment. The primary endpoint was the proportion of patients with more than 50% reduction in pad weight from baseline to 12 weeks in the provocative pad weight test. Noninferiority was established if the lower bound of the 95% CI for the treatment difference for the primary endpoint did not exceed the -5% noninferiority margin. Assuming a comparator device success rate of 52% and an NMES success rate of 71%, a sample size of 87 patients per group provided 90% power using a 1-sided type I error rate of 0.025 and a noninferiority margin of 5%. Efficacy analyses were done on the intent-to-treat population and safety analyses on the safety population (randomised patients who used the device at least once).

Study population issues: There were no statistically significant differences in baseline characteristics between the 2 groups. Most patients (67%) had SUI symptoms for more than 3 years, and most had mild (58%) or moderate (37%) SUI.

Other issues: The external NMES response rate was lower than the predicted rate (71%) used in the power calculation, so the study may have been underpowered to show non-inferiority.

Key efficacy findings

Number of patients analysed: 180 (89 external NMES, 91 intravaginal electrical stimulation)

Provocative pad weight test - proportion of patients with more than 50% reduction in pad weight from baseline at week 12 (primary endpoint)

- External NMES=56.3%
- Intravaginal electrical stimulation=63.0%, (difference -6.7%, 95% CI -21.7% to 8.4%)

Proportion of patients in the dry or mild categories of SUI severity at week 12

- External NMES=87.2%
- Intravaginal electrical stimulation=86.8%

Proportion of patients who reported improvement in SUI symptoms at week 12

- External NMES=70.7%
- Intravaginal electrical stimulation=63.0%

Pelvic organ prolapse incontinence sexual questionnaire – IUGA revised

- A trend towards improved sexual function was observed in both groups at 12 weeks.
- Mean (SD) baseline-adjusted domain scores at week 12 ranged from 0.28 (13.89) to 5.00 (10.65) in the NMES group and from -2.34 (11.45) to 5.21 (20.93) in the comparator group among sexually active women, and from 0.00 (21.08) to 11.11 (21.66) with the NMES and from -10.12 (23.09) to 9.26 (23.61) with the comparator device among non-sexually active women.

Key secondary endpoints

Parameter	External NMES			Intravaginal electrical stimulation			treatment difference, mean (SE)	95% CI
	Baseline mean (SD)	week 12, mean (SD)	change, mean (SD)	Baseline mean (SD)	week 12, mean (SD)	change, mean (SD)		
Provocative pad weight test – urine leakage, g	24.33 (20.06)	15.85 (24.49)	-8.48 (25.05)*	23.21 (20.45)	13.55 (23.19)	-9.66 (22.88)^	1.18 (3.58)	(-5.88, 8.23)
24-hour pad weight test – urine leakage, g	26.37 (32.20)	13.30 (19.58)	-13.07 (21.53)^	24.74 (28.87)	14.85 (25.62)	-9.89 (19.99)^	-3.18 (3.12)	(-9.34, 2.99)
Incontinence episodes/day	2.98 (2.34)	1.74 (2.18)	-1.24 (1.56)^	2.93 (4.99)	1.51 (2.06)	-1.43 (4.12)^	0.18 (0.47)	(-0.74, 1.11)
Incontinence Quality of Life questionnaire (total score)	58.55 (19.80)	71.97 (21.60)	13.42 (16.46)^	59.47 (19.46)	74.89 (18.14)	15.42 (18.38)^	-2.01 (2.61)	(-7.16, 3.15)
Pads used per day	2.05 (1.42)	1.75 (1.24)	-0.30 (1.00)**	1.96 (1.23)	1.52 (1.24)	-0.44 (0.98)^	0.14 (0.15)	(-0.15, 0.44)
Dryness (<1g leakage on provocative pad weight test), n (%)	0 (0)	17 (19.1)	-	0 (0)	29 (31.9)	-	-12.8 (difference in proportions at week 12)	(-25.4, -0.2)

* p=0.002, ** p=0.006, ^ p≤0.001

Device usage – median number of sessions per week

- External NMES=4.75
- Intravaginal electrical stimulation=5.92

Compliance – percent target use, mean (SD)

- External NMES=86.3 (28.8)
- Intravaginal electrical stimulation=76.5 (25.0)

Key safety findings

Device deficiencies (none led to adverse device effects)

- External NMES=11.2% (10/89)
- Intravaginal electrical stimulation=16.5% (15/91)

Proportion of patients who discontinued the study because of adverse events

- External NMES=3.4%
- Intravaginal electrical stimulation=4.4%

Device-related adverse events (adverse device effects)

Adverse event	External NMES		Intravaginal electrical stimulation	
	Number of patients (%)	Number of events	Number of patients (%)	Number of events
Total adverse events	17 (19.1)	24	11 (12.1)	13
Gastrointestinal disorders, total	0 (0)	0	1 (1.1)	1
Abdominal pain	0 (0)	0	1 (1.1)	1
General disorders or administration site conditions, total	12 (13.5)	15	2 (2.2)	2
Medical device discomfort	8 (9.0)	10	1 (1.1)	1
Medical device pain	4 (4.5)	4	1 (1.1)	1
Pain	1 (1.1)	1	0 (0)	0
Infections and infestations, total	0 (0)	0	7 (7.7)	7
Urinary tract infection	0 (0)	0	3 (3.3)	3
Vaginal infection	0 (0)	0	2 (2.2)	2

Vulvovaginal infection	0 (0)	0	2 (2.2)	2
Musculoskeletal and connective tissue disorders, total	2 (2.2)	2	0 (0)	0
Arthralgia	1 (1.1)	1	0 (0)	0
Myalgia	1 (1.1)	1	0 (0)	0
Renal and urinary disorders, total	2 (2.2)	2	0 (0)	0
Dysuria	1 (1.1)	1	0 (0)	0
Micturition urgency	1 (1.1)	1	0 (0)	0
Reproductive system and breast disorders, total	0 (0)	0	1 (1.1)	1
Vaginal discharge	0 (0)	0	1 (1.1)	1
Skin and subcutaneous tissue disorders, total	5 (5.5)	5	2 (2.2)	2
Erythema	1 (1.1)	1	0 (0)	0
Pruritus	0 (0)	0	1 (1.1)	1
Rash	1 (1.1)	1	0 (0)	0 (0)
Skin irritation	3 (3.4)	3	1 (1.1)	1

Study 2 Celenay S (2021)

Study details

Study type	Randomised controlled trial
Country	Turkey
Recruitment period	Not reported
Study population and number	n=66 (22 pelvic floor muscle exercises plus electrical stimulation, 22 pelvic floor muscle exercises plus Kinesio taping, 22 pelvic floor muscle exercises only) Women with overactive bladder, including urgency urinary incontinence (OAB-wet)
Age	Mean age (years): 49.7 (electrical stimulation), 41.3 (Kinesio taping), 44.4 (pelvic floor muscle exercises only); 100% female
Patient selection criteria	Inclusion criteria: patients diagnosed with overactive bladder in the urology outpatient clinic (age range 18 to 65) were included in the study. Exclusion criteria included pregnancy, concomitant serious cardiovascular or pulmonary diseases, uncontrolled metabolic disease (diabetes, thyroid disease), neurological problems, a concomitant malignancy, loss of sensation, mental problems to prevent evaluation and cooperation, a pacemaker, automatic implanted cardiac defibrillator, metal implant or skin lesions within the area of application of the electrodes, psoriasis, scleroderma, infection, and allergy to Kinesio tape.
Technique	Electrical stimulation device: INNOVO (Atlantic Therapeutics, Ireland). Treatment parameters: 10 Hz frequency, 250 ms pulse width, 0.5-second ramp-up and ramp-down times and 5-second contraction time. The stimulation duration and frequency were 30 minutes, 3 times a week for 6 weeks. Kinesio taping: a star shaped Kinesio tape was applied on the sacral region (S2 to S4), in standing position. This was done 2 days per week for 6 weeks. Pelvic floor muscle exercises: 1 set of exercises comprised 10 fast and 10 sustained voluntary contractions. During week 1, women were asked to do 5 sets of exercises per day, which was progressively increased by 5 sets a week until week 6. The women were instructed to do the exercises in different positions (supine, sitting, standing, and semi-squat) and to integrate them into their daily activities.
Follow up	End of treatment (6 weeks)
Conflict of interest/source of funding	None

Analysis

Follow-up issues: There was no follow up beyond the end of treatment at 6 weeks. An additional 9 patients were randomised but left the study for personal reasons (3 in each treatment group).

Study design issues: Single-blind, randomised controlled trial. Patients were randomly assigned to 1 of 3 groups according to a computer-generated random number table with random block sizes, prepared by an

independent researcher not involved in the study. For the primary outcome, patients were asked to fill out a 24-hour voiding diary for 3 days. The number of voids per day, voids per night, and incontinence episodes per day were determined by taking the average of the data over the 3 days. Symptoms were assessed with the Turkish version of the 8-item Overactive Bladder Questionnaire, which has 8 items scored from 0 to 5, giving a total score from 0 to 40, with higher scores indicating more severe symptoms. The women's perception of improvement was assessed using a 4 item Likert-type scale (worse, same, better, cured). Quality of life was assessed with the Turkish version of the King's Health Questionnaire, which consists of 21 items in 9 domains. The study sample size was calculated according to the number of voids per night. For 80% power, the calculated sample size was 22 patients per group.

Study population issues: The demographic and physical characteristics of the groups were similar except for the parity and mode of delivery. The parity was higher in the pelvic floor muscle exercise only group than in the Kinesio taping group (p=0.018), and vaginal delivery type was higher in the electrical stimulation group (84%) than in the pelvic floor muscle exercise alone group (46%).

Key efficacy findings

Number of patients analysed: 66 (22 electrical stimulation plus pelvic floor muscle exercises, 22 Kinesio taping plus pelvic floor muscle exercises, 22 pelvic floor muscle exercises only)

Comparison of symptoms and pelvic floor muscle strength scores, median (range)

Outcome	electrical stimulation, n=22	Kinesio taping, n=22	pelvic floor muscle exercises only, n=22	p value (between group)
Average number of voids/day				
Before treatment	9.0 (7.7 to 9.5)	9.8 (8.5 to 11.7)	9.3 (8.7 to 11.5)	0.183
After treatment	6.8 (5.5 to 8.0)	7.2 (6.3 to 8.0)	9.0 (8.0 to 9.7)	0.001
Within group comparison	p=0.001	p=0.001	p=0.002	
Average number of voids/night				
Before treatment	1.3 (1.0 to 2.0)	1.3 (1.0 to 2.0)	1.3 (1.0 to 2.0)	0.498
After treatment	0.7 (0.0 to 1.0)	0.3 (0.0 to 1.0)	1.0 (1.0 to 2.0)	0.002
Within group comparison	p=0.001	p=0.001	p=0.001	
Average number of incontinence episodes				
Before treatment	0.3 (0.0 to 2.5)	2.2 (0.0 to 4.0)	2.3 (1.3 to 3.3)	0.157
After treatment	0.0 (0.0 to 0.1)	0.0 (0.0 to 1.0)	1.0 (0.0 to 2.0)	0.010
Within group comparison	p=0.003	p=0.001	p=0.001	

Overactive Bladder-Version 8				
Before treatment	34.0 (29.0 to 37.0)	26.0 (18.0 to 29.0)	27.5 (23.0 to 32.0)	0.001
After treatment	6.5 (4.0 to 11.0)	9.5 (3.0 to 17.0)	21.0 (11.0 to 24.0)	0.001
Within group comparison	p=0.001	p=0.001	p=0.001	
Pelvic Floor Muscle Strength (kPa)				
Before treatment	5.0 (3.0 to 6.0)	5.0. (4.0 to 7.0)	4.5 (3.0 to 5.0)	0.314
After treatment	8.0 (6.0 to 10.0)	8.0 (7.0 to 9.0)	7.3 (5.5 to 9.0)	0.209
Within group comparison	p=0.001	p=0.001	p=0.001	

Patients' perception of improvement in symptoms, n (%), p=0.001

Perception of improvement	electrical stimulation, n=22	Kinesio taping, n=22	pelvic floor muscle exercises only, n=22
Worse	0 (0.0)	0 (0.0)	0 (0.0)
Same	0 (0.0)	0 (0.0)	9 (40.9)
Better	6 (27.3)	8 (36.4)	12 (54.5)
Cured	16 (72.7)	14 (63.6)	1 (4.5)

Quality of life scores measured on the KHQ, median (range)

Subscale of KHQ	electrical stimulation, n=22	Kinesio taping, n=22	pelvic floor muscle exercises only, n=22	p value (between group)
General health perception				
Before treatment	37.5 (25.0 to 50.0)	50.0 (25.0 to 50.0)	50.0 (50.0 to 75.0)	0.067
After treatment	25.0 (25.0 to 25.0)	25.0 (25.0 to 50.0)	50.0 (25.0 to 50.0)	0.005
p (within group)	0.021	0.015	0.005	
Incontinence impact				
Before treatment	100.0 (100.0 to 100.0)	83.3 (50.0 to 100.0)	100.0 (66.7 to 100.0)	0.032
After treatment	33.3 (33.3 to 66.7)	33.3 (11.1 to 50.0)	66.66 (33.3 to 100.0)	0.109
p (within group)	0.001	0.001	0.022	
Role limitations				

Before treatment	83.3 (66.7 to 100.0)	75.0 (50.0 to 100.0)	66.7 (33.3 to 100.0)	0.142
After treatment	25.0 (16.7 to 33.3)	16.7 (0.0 to 50.0)	33.3 (16.7 to 66.7)	0.527
p (within group)	0.001	0.001	0.002	
Physical limitations				
Before treatment	100.0 (83.3 to 100.0)	66.7 (33.3 to 100.0)	66.7 (33.3 to 100.0)	0.002
After treatment	33.3 (16.7 to 50.0)	20.8 (0.0 to 50.0)	33.3 (16.7 to 66.7)	0.347
p (within group)	0.001	0.001	0.001	
Social limitations				
Before treatment	55.6 (22.2 to 77.8)	41.7 (22.2 to 77.8)	38.9 (22.2 to 77.8)	0.649
After treatment	0.0 (0.0 to 33.3)	11.1 (0.0 to 33.3)	22.2 (11.1 to 44.4)	0.076
p (within group)	0.001	0.001	0.011	
Limitations in personal relationship				
Before treatment	16.7 (0.0 to 66.7)	29.2 (0.0 to 66.7)	0.0 (0.0 to 66.7)	0.565
After treatment	0.0 (0.0 to 0.0)	0.0 (0.0 to 25.0)	0.0 (0.0 to 33.3)	0.309
p (within group)	0.005	0.028	0.023	
Emotional problems				
Before treatment	72.2 (44.4 to 88.9)	33.3 (22.2 to 55.6)	38.9 (22.2 to 55.6)	0.004
After treatment	5.6 (0.0 to 33.3)	16.7 (0.0 to 22.2)	22.2 (0.0 to 44.4)	0.505
p (within group)	0.001	0.001	0.005	
Sleep and energy disturbances				
Before treatment	66.7 (33.3 to 66.7)	41.7 (33.3 to 66.7)	66.7 (33.3 to 100.0)	0.482
After treatment	16.7 (0.0 to 33.3)	16.7 (0.0 to 33.3)	33.3 (16.7 to 66.7)	0.018
p (within group)	0.001	0.001	0.003	
Severity measures				
Before treatment	50.0 (33.3 to 73.3)	40.0 (25.0 to 80.0)	70.00 (40.0 to 86.7)	0.412
After treatment	6.7 (0.0 to 20.0)	22.5 (13.3 to 46.7)	36.7 (20.0 to 60.0)	0.001
p (within group)	0.001	0.001	0.001	
Symptom severity				
Before treatment	15.5 (13.0 to 19.0)	12.5 (10.0 to 16.0)	14.0 (9.0 to 17.0)	0.017
After treatment	1.5 (0.0 to 4.0)	4.5 (2.0 to 7.0)	10.0 (6.0 to 12.0)	0.001
p (within group)	0.001	0.001	0.001	

Key safety findings

No patient reported any adverse effects.

Study 3 Correia G (2014)

Study details

Study type	Randomised controlled trial
Country	Brazil
Recruitment period	2012 to 2013
Study population and number	n=45 (15 surface electrical stimulation, 15 intravaginal electrical stimulation, 15 control) Women with SUI
Age	Mean age (years): 64.5 (surface stimulation), 59.9 (intravaginal stimulation), 60.1 (control); 100% female
Patient selection criteria	Inclusion criteria: women aged over 50 years, with urinary leakage on stress who had not had physical therapy for UI. Women with symptoms of urgency UI and mixed UI were excluded. Two questions were used to determine patient eligibility. The first question was: ‘‘During the past month, have you involuntarily got wet while performing some kind of physical exertion, e.g. coughing, lifting, sneezing or laughing?’’ The second question was: ‘‘During the past month, have you experienced such a strong urge to urinate that it was impossible to get to the toilet in time?’’ Only women who answered ‘‘yes’’ just to the first question were recruited. Exclusion criteria included latex allergies, vaginal or urinary infections, pelvic organ prolapse greater than grade 2, inability to do voluntary pelvic floor muscle contraction, cognitive or neurological disorder, uncontrolled hypertension, inability to carry out the evaluation or treatment, hormone therapy, use of pacemaker or metal rod implantation
Technique	Surface stimulation and intravaginal stimulation: 12 individual sessions, 2 weekly sessions of 20 minutes with Dualpex 961 (Quark Medical Products) equipment. The same stimulation parameters were used in both groups (frequency: 50 Hz; pulse duration: 700 ms; time: 20 min; 4-seconds on/8-seconds off cycles; rise: 2 seconds fall: 2 seconds; stimulation intensity: maximal level tolerable). In the surface stimulation group, the women were positioned supine, with 45° of hip and knee flexion. Four surface electrodes of silicone were fixed with masking tape, 2 were placed in the suprapubic region and the other 2 were crossed on the skin and fixed medial to the ischial tuberosity. During the treatment the women used panties. In the intravaginal stimulation group, the women were positioned supine with 45° of hip and knee flexion for the positioning of an intravaginal electrode. During the treatment the women were positioned supine with hip and knee in a neutral position. Women in the control group had no treatment during the study period. Afterwards, they were referred for physical therapy treatment.
Follow up	End of treatment
Conflict of interest/source of funding	Funding support came from Sao Paulo Research Foundation, Coordination for the Improvement of Higher Education Personnel and Brazilian National Research Council.

Analysis

IP overview: Transcutaneous electrical neuromuscular stimulation for urinary incontinence

Follow-up issues: There was no follow up beyond the end of the treatment period. An additional 3 patients were randomised but were lost to follow up and were excluded from the analysis.

Study design issues: Prospective single centre randomised controlled trial. Patients were randomised into 3 groups using computer-generated random numbers. A researcher who was not involved in the data collection or analyses created the randomisation list. The main outcomes were urinary leakage, pressure and strength of pelvic floor muscle contraction. The secondary outcome was quality of life evaluated by the KHQ. The sample size was calculated considering the values of pad test (in grams) from previous data on a pilot study of surface electrical stimulation treatment. At a significance level of 5% and power of 90%, it was estimated to need a sample of at least 45 people. A blinded experienced physiotherapist did all evaluations.

Study population issues: There were no statistically significant baseline differences between the groups regarding age, body mass index, number of deliveries and number of vaginal deliveries.

Key efficacy findings

Number of patients analysed: 45 (15 surface electrical stimulation, 15 intravaginal stimulation, 15 control)

Urinary leakage and pelvic floor muscle strength before and after treatment, mean (SD)

Outcome	Treatment group	Before treatment	After treatment	Intragroup p value
1 hour pad test (g)	Surface stimulation	6.28 (15.19)	3.31 (12.10)	0.010
	Intravaginal stimulation	2.20 (4.65)	0.41 (0.78)	0.010
	Control	7.33 (16.02)	7.62 (15.27)	0.61
	Intergroup p value	0.18	0.0005	
Muscle strength	Surface stimulation	2.06 (0.80)	2.53 (0.83)	0.07
	Intravaginal stimulation	2.00 (1.00)	2.66 (0.81)	0.007
	Control	2.16 (0.83)	2.25 (0.86)	0.99
	Intergroup p value	0.95	0.29	
Pressure (cmH_2O)	Surface stimulation	39.41 (17.65)	47.37 (19.16)	0.004
	Intravaginal stimulation	37.42 (22.89)	44.23 (20.10)	0.04
	Control	37.92 (22.95)	37.65 (19.16)	0.58
	Intergroup p value	0.74	0.52	

Values for KHQ domains before and after treatment, mean (SD)

Outcome	Treatment group	Before treatment	After treatment	Intragroup p value
General health	Surface stimulation	40.00 (26.39)	33.33 (32.27)	0.68
	Intravaginal stimulation	38.33 (18.58)	26.66 (17.59)	0.07

	Control	37.50 (25.00)	43.75 (21.65)	0.61
	Intergroup p value	0.74	0.17	
Incontinence impact	Surface stimulation	57.78 (32.04)	6.66 (13.80)	0.0005
	Intravaginal stimulation	64.44 (32.03)	4.44 (11.73)	0.0005
	Control	58.33 (37.94)	61.11 (37.15)	0.44
	Intergroup p value	0.80	<0.0001	
Limitations of daily activities	Surface stimulation	34.44 (42.00)	0.00 (0.00)	0.01
	Intravaginal stimulation	36.66 (26.12)	0.00 (0.00)	0.001
	Control	56.94 (39.85)	54.16 (40.27)	1.00
	Intergroup p value	0.39	<0.0001	
Physical limitations	Surface stimulation	43.33 (31.37)	1.11 (4.30)	0.0003
	Intravaginal stimulation	43.33 (39.74)	1.11 (4.30)	0.004
	Control	54.16 (44.45)	51.38 (42.91)	0.68
	Intergroup p value	0.52	<0.0001	
Social limitations	Surface stimulation	18.52 (32.71)	1.85 (5.00)	0.22
	Intravaginal stimulation	21.48 (31.83)	0.00 (0.00)	0.02
	Control	33.79 (34.85)	31.01 (36.19)	0.68
	Intergroup p value	23	0.0007	
Personal relationships	Surface stimulation	4.44 (11.73)	0.00 (0.00)	0.47
	Intravaginal stimulation	13.33 (35.74)	0.00 (14.08)	0.22
	Control	13.88 (23.39)	22.22 (33.58)	1.00
	Intergroup p value	0.35	0.04	
Emotions	Surface stimulation	28.15 (38.23)	2.96 (8.88)	0.01
	Intravaginal stimulation	48.15 (33.77)	2.96 (7.82)	0.0008
	Control	49.07 (32.29)	56.48 (33.65)	0.75
	Intergroup p value	0.1548	<0.0001	
Sleep and disposition	Surface stimulation	27.77 (41.62)	0.00 (0.00)	0.02
	Intravaginal stimulation	14.44 (28.08)	0.00 (0.00)	0.07
	Control	30.55 (43.13)	30.55 (43.13)	0.68
	Intergroup p value	0.8140	0.003	
Severity measures	Surface stimulation	37.77 (29.67)	8.09 (14.60)	0.0005
	Intravaginal stimulation	38.66 (21.56)	1.77 (4.69)	0.0003
	Control	47.22 (26.12)	58.33 (25.60)	0.75
	Intergroup p value	0.7605	<0.0001	

Key safety findings

None reported

IP overview: Transcutaneous electrical neuromuscular stimulation for urinary incontinence

Study 4 Karaman E (2020)

Study details

Study type	Randomised controlled trial
Country	Turkey
Recruitment period	2019 to 2020
Study population and number	n=48 (20 external NMES and Kegel exercises, 28 Kegel exercises only) Patients who had surgery for SUI
Age and sex	Mean age 42 years; 100% female
Patient selection criteria	Patients diagnosed with predominantly SUI who had anti-incontinence surgery were included. Exclusion criteria included patients who had chronic severe diseases, cardiac pacemakers, neurological or psychiatric disorders or urinary tract infections. Patients who were pregnant were also excluded.
Technique	NMES device: INNOVO All patients had anti-incontinence surgery (39 had a transvaginal tape procedure, 7 had a transobturator tape procedure and 2 had Burch colposuspension). All patients were taught how to do Kegel exercises (at least 3 sets of 10 to 15 repetitions a day for 1 month during the study period). Patients had either electrical stimulation (for 30 minutes twice a week) together with Kegel exercises or Kegel exercises only for 4 weeks after their surgery.
Follow up	End of treatment (4 weeks)
Conflict of interest/source of funding	The study was supported by the Van Yuzuncu Yil University, Department of Scientific Research Project.

Analysis

Follow-up issues: there was no follow up beyond the end of the treatment period of 4 weeks.

Study design issues: Prospective single centre randomised controlled trial. The main aim was to evaluate the effect of functional electrical stimulation therapy on SUI recurrence and quality of life of patients in the postoperative period after anti-incontinence surgery. Patients were randomised into 2 groups after their surgery, according to given sequential numbers. A bladder diary diagram was used to assess urinary leakage during the last 3 days of the month. Quality of life was assessed by a patient-completed questionnaire at the end of treatment (using Wagner's quality of life scale, with higher scores denoting worse quality of life). The 24-hour pad test was used as an objective measure of urinary leakage.

Study population issues: The 2 groups were comparable in terms of baseline demographic characteristics and clinical features. There were no statistically significant differences in mean parity number, body mass index, smoking status and number of previous vaginal births.

Key efficacy findings

Number of patients analysed: 48 (20 external NMES plus Kegel exercises, 28 Kegel exercises only)

Clinical outcomes at end of treatment period

Clinical outcome	External NMES plus Kegel exercises, n=20	Kegel exercises only, n=28	p value
Patients with recurrence of urinary incontinence, n (%)	2 (10%)	5 (17.8%)	0.02
24-hour pad test, g, mean (SD)	5.4 (4.2)	7.4 (6.4)	0.169
Number of urine leakages in 24-hour bladder diary, mean (SD)	1.6 (1.2)	3.2 (1.8)	0.03
Quality of life score, mean (SD)	7.3 (6.2)	18.4 (6.52)	0.01

Key safety findings

None reported.

Study 5 Guo G (2018)

Study details

Study type	Randomised controlled trial
Country	China (2 centres)
Recruitment period	2016 to 2018
Study population and number	n=82 (41 external NMES, 41 sham) Patients with urinary incontinence after stroke
Age and sex	Mean age (years): 64.2 (external NMES), 62.5 (sham) p=0.50; 43% (35/82) female
Patient selection criteria	Patients with urinary incontinence after stroke were diagnosed according to the Diagnosis Criteria of the American Stroke Association and International Continence Society. All patients aged 40 to 75 years were included in the study. In addition, all patients had more than 6 months duration of stroke; and urinary incontinence after the stroke; normal consciousness, effectively communication; and written informed consent. Exclusion criteria included urinary retention; urinary incontinence caused by other diseases (such as spinal injury, multiple sclerosis); acute or chronic urinary incontinence before the stroke; severe diseases of important organs, such as heart, liver, kidney; psychological disorders; taken other medications that affected the urinary incontinence; pregnancy or breastfeeding; received electrical stimulation, such as NMES, or electroacupuncture 2 months before the study; or patients who did not agree to continue the study.
Technique	NMES device: portable NMES stimulator (Globus ACTIVA 600 Pro, Globus, Italy). The device has 2 electrode pads. The positive pad was placed at the region of the second sacral level on opposite sides of the vertebral column. The negative pad was placed at the inside of the middle and lower third of the junction between the posterior superior iliac spine and the ischial node. Treatment parameters: 50 Hz frequency, 250ms pulse duration, and 10 seconds on and 30 seconds off for 30 minutes each session, once daily, 5 sessions weekly for a total of 10 weeks. Patients in the sham group had sham NEMS at the same location, treatment protocol, using same NMES device, but without an active probe.
Follow up	To end of treatment (10 weeks)
Conflict of interest/source of funding	None

Analysis

Follow-up issues: There was no follow up beyond the end of the treatment period. Of the 82 randomised patients, 4 (5%) were lost to follow up, 2 in each group. An additional 4 patients withdrew consent (1 in the NMES and 3 in the sham arm). All primary and secondary efficacy endpoints were measured at baseline and at the end of 10 weeks treatment.

Study design issues: Randomised sham-controlled trial. Patients were allocated randomly to a NMES group or a sham group by a statistician. All randomisation and allocation information were concealed in opaque, sealed envelopes. All investigators were masked to the randomisation assignment and allocation. The outcome assessors and data analysts were also blinded. The primary efficacy endpoints were measured by the urodynamic outcome, and Overactive Bladder Symptom Score (total score ranges from 0 to 15, with higher scores indicating more severe symptoms). An intention-to-treat approach was used.

Study population issues: There were no statistically significant differences regarding all baseline values between the 2 groups. These values included age, sex, body mass index, duration of stroke, duration of urinary incontinence, disease types, region, co-morbidities, and outcome measurements at baseline.

Key efficacy findings

Number of patients analysed: 82 (41 external NMES, 41 sham)

Urodynamic values after 10-week treatment, mean change from baseline (range)

Urodynamic values	External NMES, n=41	Sham, n=41	difference	p value
Maximum cystometric capacity, ml	105.3 (76.5 to 142.8)	10.3 (3.1 to 13.9)	95.6 (81.2 to 120.4)	<0.01
Detrusor pressure, cmH_2O	-11.8 (-19.4 to -6.6)	-1.7 (-2.6 to -0.8)	-10.2 (-13.7 to -8.1)	<0.01
Maximum flow rate, ml/second	8.9 (5.6 to 12.3)	0.4 (-0.5 to 1.0)	8.5 (6.3 to 10.1)	<0.01

Overactive Bladder Symptom Score after 10-week treatment

Overactive Bladder Symptom Score	External NMES, n=41	Sham, n=41	difference	p value
After treatment, mean (SD)	8.1 (3.4)	12.3 (3.0)	-	<0.01
Difference from baseline, mean (range)	-4.5 (-6.1 to -2.7)	-0.5 (-1.0 to -0.1)	-4.0 (-5.2 to -2.9)	<0.01

ICIQ-SF Score after 10-week treatment

ICIQ-SF Score	External NMES, n=41	Sham, n=41	difference	p value
After treatment, mean (SD)	7.8 (3.3)	10.5 (3.1)	-	<0.01
Difference from baseline, mean (range)	-3.8 (-5.0 to -2.2)	-0.6 (-1.2 to -0.2)	-3.3 (-4.7 to -2.4)	<0.01

Barthel Index after 10-week treatment

Barthel index	External NMES, n=41	Sham, n=41	difference	p value
After treatment, mean (SD)	15.7 (3.1)	11.1 (3.4)	-	<0.01
Difference from baseline, mean (range)	5.3 (2.4 to 7.7)	0.3 (0.1 to 0.6)	5.1 (2.8 to 7.2)	<0.01

Key safety findings

There were no adverse effects in either group.

Study 6 Pané-Alemany R (2021)

Study details

Study type	Randomised controlled trial
Country	Spain
Recruitment period	2019
Study population and number	n=70 (35 surface electrodes, 35 intra-anal probe) Men with persistent stress urinary incontinence after radical prostatectomy
Age and sex	Mean age 62.8 years; 100% (70/70) male
Patient selection criteria	Men with persistent stress urinary incontinence after radical prostatectomy were included. Patients with the following were excluded: pharmacological treatment for urinary incontinence, anatomical malformations of the pelvic floor musculature, a pacemaker, anal fistulas, serious psyche disorders, a history of lower urinary tract infections, required radiotherapy as adjuvant treatment, urethral stricture after surgery, pelvic floor denervation, or neuromuscular diseases.
Technique	Transcutaneous electrical stimulation: Neurotrac Pelvitone® muscular electrostimulator was used. Two round surface electrodes were stuck to the patients' perineum and at the base of their penis. Intra-anal probe: Analys Plus® anal stimulation probe. Selected treatment parameters included 10 minutes of biphasic intermittent current, frequency 30 Hz, pulse width 0.25 ms, and current intensity between 10 and 30 mA, with no on–off cycles. Additionally, a total of 5 minutes extra stimulation at a frequency of 50 Hz, pulse width 0.25 ms, and current intensity between 1 and 50mA was given, with individually adapted on-off (duty) cycles based on each man's ability to hold a voluntary contraction. On time ranged from 0.5 to 10 seconds, and off time from 10 to 30 seconds. If the ability to hold the contraction improved, the duty cycle was progressed each month. All patients were encouraged to tolerate as high an intensity as possible to get a contraction. A total of 10 treatment physiotherapy sessions were held on a weekly basis. Kegel active exercises were done under the supervision and correction of the physiotherapist in each of the treatment sessions and also at home in both groups.
Follow up	End of treatment (10 weeks)
Conflict of interest/source of funding	None

Analysis

Follow-up issues: There was no follow up beyond the end of the treatment period. Of the 70 patients, 4 (5.7%) were lost to follow up (2 in each group).

Study design issues: Randomised controlled trial held at a pelvic floor specialised physiotherapy centre and a pelvic floor rehabilitation unit. Patients were randomised 1:1 into 2 groups using Sealed Envelope Ltd. 2015 online randomisation. The sample size was estimated to give 80% power, including 10% losses to follow up. The established equivalence range was between −22 and 22 g of urine loss. The estimation was made using weight leakage (24 hour pad test) as the main variable. Equivalence was assessed by estimating the difference (along with its 90% CI) between initial and final urine leakage mean values. The analysis was done per protocol and by intention-to-treat.

Study population issues: The baseline characteristics were similar between the 2 groups.

Other issues: there is some discrepancy between the baseline pad weight values reported in the tables in the publication. The figures below have been taken from table 2A, which also includes follow up results.

Key efficacy findings

Number of patients analysed: 70 (35 surface electrodes, 35 intra-anal probe)

Urine weight leakage on 24-hour pad test after 5 and 10 weeks of treatment – per-protocol

	Surface electrodes group, n=33	Intra-anal probe group, n=33
Baseline pad weight, g, mean (SD)	335.2 (418.0)	324.4 (440.1)
Week 5, mean (SD)	202.8 (274.6)	200.3 (347.5)
Difference (90% CI)	132.5 (71.6 to 193.3)	124.1 (69.2 to 179.1)
p value	0.001	0.001
Baseline pad weight, g, mean (SD)	335.2 (418.0)	324.4 (440.1)
Week 10	103.4 (182.6)	79.2 (182.4)
Difference (90% CI)	231.9 (134.4 to 329.3)	245.2 (149.6 to 340.7)
p value	<0.001	<0.001

Urine weight leakage on 24-hour pad test after 5 and 10 weeks of treatment – intent-to-treat

	Surface electrodes group, n=35	Intra-anal probe group, n=35
Baseline pad weight, g, mean (SD)	355.9 (428.9)	310.5 (431.1)
Week 5, mean (SD)	196.8 (727.6)	188.8 (340.5)
Difference (90% CI)	159.1 (84.9 to 233.3)	121.7 (69.8 to 181.5)
p value	0.001	<0.001
Baseline pad weight, g, mean (SD)	346.0 (426.5)	310.5 (431.1)
Week 10	97.5 (178.8)	74.7 (177.9)
Difference (90% CI)	248.5 (148.3 to 348.8)	235.8 (145.2 to 326.4)
p value	<0.001	<0.001

IP overview: Transcutaneous electrical neuromuscular stimulation for urinary incontinence

The differences in urine loss between the intra-anal group and the surface group were not statistically significant.

Changes in quality of life after 10 weeks of treatment – per-protocol

Outcome measure	Surface electrodes group, n=33				Intra-anal probe group, n=33			
	Baseline, mean (SD)	week 10, mean (SD)	Difference (90% CI)	p	Baseline, mean (SD)	Week 10, mean (SD)	Difference (90% CI)	p
ICIQ-SF	15.2 (3.8)	11.2 (5.4)	4.0 (2.6 to 5.5)	<0.001	13.6 (4.9)	9.2 (5.7)	4.4 (3.0 to 5.7)	<0.001
I-QOL	55.7 (24.9)	29.1 (26.7)	26.6 (20.1 to 33.0)	<0.001	51.9 (31.2)	29.6 (26.2)	22.4 (15.7 to 29.0)	<0.001
SF-12 (mental)	2.3 (3.7)	3.9 (3.9)	-1.7 (-2.8 to -0.5)	0.017	1.4 (3.7)	3.1 (3.2)	-1.7 (-2.4 to -1.1)	<0.001
SF-12 (physical)	6.4 (37)	8.5 (4.5)	-2.2 (-3.1 to -1.2)	<0.001	4.9 (4.1)	7.8 (4.2)	-2.9 (-3.9 to -1.8)	<0.001

Changes in quality of life after 10 weeks of treatment – intent-to-treat

Outcome measure	Surface electrodes group, n=33				Intra-anal probe group, n=33			
	Baseline, mean (SD)	week 10, mean (SD)	Difference (90% CI)	p	Baseline, mean (SD)	Week 10, mean (SD)	Difference (90% CI)	p
ICIQ-SF	15.4 (3.8)	11.6 (5.5)	3.8 (2.4 to 5.2)	<0.001	13.7 (4.7)	9.5 (5.7)	4.1 (2.8 to 5.5)	<0.001
I-QOL	56.5 (25)	31.4 (28.2)	25.1 (18.7 to 31.4)	<0.001	53.2 (30.9)	32.1 (27.7)	21.1 (14.6 to 27.5)	<0.001
SF-12 (mental)	2 (3.7)	3.6 (4.0)	-1.6 (-2.6 to -0.5)	0.017	1.3 (3.7)	2.9 (3.2)	-1.6 (-2.3 to -1.0)	<0.001
SF-12 (physical)	6.3 (3.7)	8.3 (4.5)	-2 (-2.9 to -1.2)	<0.001	5.1 (4.0)	7.7 (4.1)	-2.7 (-3.7 to -1.7)	<0.001

Key safety findings

No serious adverse events were recorded during the trial. Overall adherence to treatment was 94.3%, with no statistically significant difference between the two study groups.

Study 7 Shen S (2018)

Study details

Study type	Non-randomised comparative study
Country	China
Recruitment period	2014 to 2017
Study population and number	n=163 (103 external NMES and pelvic muscle exercises, 60 pelvic muscle exercises only) Women with post-stroke urinary incontinence
Age and sex	Mean age (years): 58.6 (external NMES), 56.4 (control) p=0.21; 100% female
Patient selection criteria	All patients were confirmed diagnosed with post-stroke urinary incontinence by the diagnosis criteria of the American Stroke Association and the International Continence Society. Exclusion criteria included pregnancy, unconsciousness, psychiatric problems, severe organ diseases, having a cardiac pacemaker, or lack of communication ability and recognition. In addition, patients were also excluded if they had electrical stimulation therapy, including electroacupuncture 1 month before the study. Patients with incomplete information were also excluded.
Technique	Device: NMES device (HANS-100, Nanjing Jisheng Medical Technology Co., Ltd) The device had 2 gel pads attached to a silicon patch, which were attached to the selected local bilateral acupoint area (over the first, second, third and fourth sacral foramen, and lateral to the posterior midline, on the level of the tip of the coccyx) for 30 minutes daily, each pair of points 6 minutes, 3 times weekly for a total of 8 weeks. Frequency was 2 to 100 Hz and the current intensity was gradually increased to the maximum tolerance for each patient. All patients were asked to practice pelvic muscle exercises for 5 minutes a day for 8 weeks.
Follow up	End of treatment (8 weeks)
Conflict of interest/source of funding	None

Analysis

Follow-up issues: There was no follow up beyond the end of the treatment period. Results at 4 and 8 weeks were presented for all patients.

Study design issues: Retrospective, single centre, non-randomised comparative study. Outcome measures included the amount of urine leakage, urinary symptoms, and quality of life. The amount of urine leakage was measured by the 1-hour pad test. Urinary symptoms were measured by the BFUSQ score, with a higher score meaning worse condition or quality of life, and quality of life was measured by the ICIQ-SF score. The data analyst was blinded to treatment group allocation.

Study population issues: There were no statistically significant differences in baseline characteristics between the 2 groups.

Key efficacy findings

Number of patients analysed: 163 (103 NMES plus pelvic muscle exercises, 60 pelvic muscle exercises only)

Comparison of outcome measurements after 4-week treatment (change from before treatment); mean (range)

Outcome	NMES group	Control group	Difference	p value
Urine leakage, mL	-6.5 (-9.1 to -4.2)	-4.5 (-7.3 to -2.0)	-2.0 (-3.5 to -0.9)	0.07
BFUSQ score: inconvenience in activities of daily life	-9.3 (-12.6 to -7.5)	-7.1 (-9.2 to -5.9)	-2.2 (-3.7 to -1.0)	0.10
BFUSQ score: urinary symptoms	-3.0 (-5.0 to -2.2)	-1.9 (-3.4 to -0.8)	-1.0 (-1.8 to -0.4)	0.25
ICIQ-SF score	-1.8 (-2.7 to -1.0)	-0.9 (-1.7 to -0.3)	-0.8 (-1.3 to -0.3)	0.19

Comparison of outcome measurements after 8-week treatment (change from before treatment); mean (range)

Outcome	NMES group	Control group	Difference	p value
Urine leakage, mL	-10.9 (-13.4 to -7.2)	-5.0 (-7.9 to -2.6)	-6.0 (-8.1 to -4.3)	<0.01
BFUSQ score: inconvenience in activities of daily life	-21.7 (-24.9 to -17.7)	-8.6 (-10.5 to -6.4)	-13.1 (-16.2 to -9.9)	<0.01
BFUSQ score: urinary symptoms	-7.3 (-10.1 to -4.9)	-2.5 (-4.2 to -1.1)	-4.8 (-6.3 to -3.3)	<0.01
ICIQ-SF score	-4.2 (-6.6 to -2.5)	-1.3 (-2.4 to -0.6)	-2.9 (-4.1 to -1.6)	<0.01

Key safety findings

No adverse events were recorded in either group during the 8-week treatment period.

Study 8 Kolb G (2019)

Study details

Study type	Cohort study
Country	US
Recruitment period	Not reported
Study population and number	n=20 Women with mild or moderate SUI
Age and sex	Mean age 46.4 years (range 18 to 80 years); 100% female
Patient selection criteria	Inclusion criteria for symptom severity were a self-reported minimum of 2 urinary incontinence episodes per 36 hours and no more than 5 urinary incontinence episodes per 24 hours. Exclusion criteria included current or recent pregnancy, recent pelvic surgery, body mass index more than 30 kg/m^2, active urinary tract infection, an implanted cardiac device or cardiac condition, and predominant urge urinary incontinence.
Technique	Device: Elitone (Elidah, US) The device delivers electrical muscle stimulation through the perineal region. It is composed of 2 components, a disposable electrode and a reusable control unit. The thin electrode has an hourglass shape and fits the perineal region, with the anterior end positioned proximate the pubic symphysis and the posterior end positioned near the ischial tuberosities. Four electrically conductive regions positioned at the extents of the electrode use hydrogel to adhere the device to the skin and transmit electrical stimulation to the adjacent tissues. Patients can wear clothes over the device and resume other activities while having treatment. The device delivers a defined treatment regimen comprising 4 seconds of stimulation at 50 Hz, 2 seconds of stimulation at 10 Hz, and 6 seconds of relaxation, after which the cycle is repeated for a total of 20 minutes. Patients were instructed to self-administer the pre-programmed 20-minute treatment sessions 4 to 5 times per week for 6 weeks.
Follow up	End of treatment (6 weeks)
Conflict of interest/source of funding	2 of the 4 authors have principal ownership in Elidah, the manufacturer of the device under investigation and 1 author provides consulting services for Elidah.

Analysis

Follow-up issues: there was no follow up beyond the end of the treatment period of 6 weeks. An additional 9 women entered the study, but 5 were lost to follow up, 1 stopped the study because of time constraints, and 3 were excluded from the analysis because they did not meet the criteria of mild or moderate SUI.

Study design issues: Single-centre cohort study. Participants were recruited from the senior author's practice and through social media advertisements. After providing informed consent, participants were sent a device with a user manual, a description of the patient protocol, pre- and post-treatment questionnaires, and a daily

log. The main outcome measures were the reduction in incontinence episodes per day, a favourable change in the I-QoL survey score, and a reduction in pad use. A reduction of 50% or more in leaks per day, a change in 2.5 points on the I-QoL survey score and 50% reduction in pad usage (in those people who reported regular pad usage before the study) were used to define responders.

Study population issues: Half of the participants had pure SUI and the other half had mixed incontinence with predominant SUI symptoms. 65% of women had previously completed a regimen of Kegel exercises or other pelvic floor therapy without satisfactory results.

Other issues: Mean treatment frequency started at 5.1 treatments per week and reduced to 4.3 in the sixth week.

Key efficacy findings

Number of patients analysed: 20

- Reduction in leaks per day=71%
- Proportion of women with clinically significant reduction in leakage episodes=75%
- Proportion of women with clinically significant improvement in I-QoL score=85%
- Proportion of women using pads regularly with clinically significant reduction in pad usage=67%
- Proportion of women who were satisfied with their treatment=83%
- All women reported that the electrode shape and stimulation were comfortable.

Paired sample t-test statistics for changes in daily leakage, I-QoL score, and daily pad usage

Outcome Measure	n (pairs)	Before treatment mean (SD)	End of treatment mean (SD)	SE of difference	95% CI of difference	t value	p value
Leaks per day	20	1.84 (1.04)	0.58 (0.73)	0.21	0.82 to 1.70	6.02	<0.0001
I-QoL score	20	70.3 (18.0)	84.8 (17.4)	3.21	-21.3 to -7.8	4.54	<0.0002
Pads per day	15	1.8 (1.1)	0.8 (0.8)	0.25	0.46 to 1.54	3.94	<0.001

Key safety findings

The paper states that no adverse events were reported that resulted in an injury or health risk.

Validity and generalisability of the studies

- The studies in the key evidence were based in the US, Turkey, Spain, Brazil, China and South Korea.
- Several randomised controlled trials were identified, 1 of which was sham-controlled (Guo et al., 2018).
- Two randomised controlled trials compared transcutaneous NMES with intravaginal electrical stimulation (Dmochowski et al., 2019 and Correia et al., 2014). One compared transcutaneous electrical stimulation with intra-anal electrical stimulation (Pané-Alemany et al., 2021).
- One randomised controlled trial assessed the effect of transcutaneous NMES on SUI recurrence in the 4 weeks after anti-incontinence surgery (Karaman et al., 2020).
- Of the 8 studies, 4 included women with SUI. One study included men who had SUI after radical prostatectomy and 1 included women with overactive bladder who had urinary urge incontinence. Two studies included people with post-stroke urinary incontinence (1 included men and women and 1 included only women).
- None of the 8 studies reported follow up outcomes beyond the end of the treatment period.
- Different devices were used in the studies, with different treatment parameters and different placement of electrodes.

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

Related NICE guidance

Below is a list of NICE guidance related to this procedure.

Interventional procedures

- Transvaginal laser therapy for stress urinary incontinence. NICE interventional procedures guidance 696 (2021). Available from http://www.nice.org.uk/guidance/IPG696
- Extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence in women. NICE interventional procedures guidance 576 (2017). Available from http://www.nice.org.uk/guidance/IPG576
- Single-incision short sling mesh insertion for stress urinary incontinence in women. NICE interventional procedures guidance 566 (2016). Available from http://www.nice.org.uk/guidance/IPG566
- Percutaneous posterior tibial nerve stimulation for overactive bladder syndrome. NICE interventional procedures guidance 362 (2010). Available from http://www.nice.org.uk/guidance/IPG362
- Intramural urethral bulking procedures for stress urinary incontinence in women. NICE interventional procedures guidance 138 (2005). Available from http://www.nice.org.uk/guidance/IPG138
- Sacral nerve stimulation for urge incontinence and urgency-frequency. NICE interventional procedures guidance 64 (2004). Available from http://www.nice.org.uk/guidance/IPG64

Medical technologies

- Axonics sacral neuromodulation system for treating refractory overactive bladder. NICE medical technologies guidance 50 (2020). Available from http://www.nice.org.uk/guidance/MTG50

NICE guidelines

- Urinary incontinence and pelvic organ prolapse in women: management. NICE guideline 123 (2019). Available from http://www.nice.org.uk/guidance/NG123

- Urinary incontinence in neurological disease: assessment and management. NICE clinical guideline 148 (2012). Available from http://www.nice.org.uk/guidance/CG148
- Lower urinary tract symptoms in men: management. NICE clinical guideline 97 (2010; last updated 2015). Available from http://www.nice.org.uk/guidance/CG97

Additional information considered by IPAC

Professional experts' opinions

Expert advice was sought from consultants who have been nominated or ratified by their professional Society or Royal College. The advice received is their individual opinion and is not intended to represent the view of the society. The advice provided by professional experts, in the form of the completed questionnaires, is normally published in full on the NICE website during public consultation, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

Two professional expert questionnaires were submitted and can be found on the NICE website.

Patient commentators' opinions

NICE's Public Involvement Programme was unable to gather patient commentary for this procedure.

Company engagement

A structured information request was sent to 1 company who manufactures a potentially relevant device for use in this procedure. NICE received 1 completed submission. This was considered by the IP team and any relevant points have been taken into consideration when preparing this overview.

Issues for consideration by IPAC

- Studies that described intracavity electrical stimulation as the intervention, using intravaginal or anal probes, were not included.

- Studies that aimed to directly stimulate nerves (transcutaneous electrical nerve stimulation) were not included.
- Studies that only included children were not included.

References

1. Dmochowski R, Lynch CM, Efros M et al. (2019) External electrical stimulation compared with intravaginal electrical stimulation for the treatment of stress urinary incontinence in women: A randomized controlled noninferiority trial. Neurourology and Urodynamics 38: 1834–43
2. Celenay ST, Karaaslan Y, Coban O et al. (2021) A comparison of Kinesio taping and external electrical stimulation in addition to pelvic floor muscle exercise and sole pelvic floor muscle exercise in women with overactive bladder: a randomized controlled study. Disability and Rehabilitation 1–9
3. Correia GN, Pereira VS, Hirakawa HS et al. (2014) Effects of surface and intravaginal electrical stimulation in the treatment of women with stress urinary incontinence: randomized controlled trial. European Journal of Obstetrics, Gynecology, and Reproductive Biology 173: 113–8
4. Karaman E, Kolusari A, Kaplan S (2020) The effect of neuromuscular electrical stimulation therapy on stress urinary incontinence recurrence: a randomized prospective study. Eastern Journal of Medicine 25: 506–12
5. Guo G-Y, Kang Y-G (2018) Effectiveness of neuromuscular electrical stimulation therapy in patients with urinary incontinence after stroke: A randomized sham controlled trial. Medicine 97: e13702
6. Pane-Alemany R, Ramírez-García I, Kauffmann S et al. 2021. Efficacy of transcutaneous perineal electrostimulation versus intracavitary anal electrostimulation in the treatment of urinary incontinence after a radical prostatectomy: Randomized controlled trial. Neurourology & Urodynamics 40: 1761–69
7. Shen S-X, Liu Y (2018) A retrospective study of neuromuscular electrical stimulation for treating women with post-stroke incontinence. Medicine 97: e11264
8. Kolb G, Kolb E, Richmond C et al. (2019) Surface-applied electrical muscle stimulation for self-administered treatment of female stress urinary incontinence. Journal of Women's Health Physical Therapy 43: 188–93

Literature search strategy

Databases	Date searched	Version/files
MEDLINE (Ovid)	08/04/2022	1946 to April 07, 2022
MEDLINE In-Process (Ovid)	08/04/2022	1946 to April 07, 2022
MEDLINE Epubs ahead of print (Ovid)	08/04/2022	April 07, 2022
EMBASE (Ovid)	08/04/2022	1974 to 2022 April 07
EMBASE Conference (Ovid)	08/04/2022	1974 to 2022 April 07
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	08/04/2022	Issue 3 of 12, March 2022
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	08/04/2022	Issue 3 of 12, March 2022
International HTA database (INAHTA)	08/04/2022	-

Trial sources searched

- Clinicaltrials.gov
- ISRCTN
- WHO International Clinical Trials Registry

Websites searched

- National Institute for Health and Care Excellence (NICE)
- NHS England
- Food and Drug Administration (FDA) - MAUDE database
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- General internet search

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

Literature search strategy

Number	Search term
1	exp urinary incontinence/
2	((urin* or bladder) adj4 (incontine* or leak* or wetting*)).tw.
3	((stress* or mix* or urg*) adj4 incontinen*).tw.
4	Urinary Bladder, Overactive/
5	(bladder* adj4 overactiv*).tw.

6	(detrusor* adj4 (instabili* or overactiv*)).tw.
7	(sphincter adj4 (defic* or dysfunct*)).tw.
8	(detrusor* adj4 (instabili* or overactiv*)).tw.
9	((urinary adj4 frequency) or (urinary adj4 urgency)).tw.
10	(OAB or UUI or SUI).tw.
11	or/1-10
12	multipath*.tw.
13	(non-implant* or non-vaginal or non-invasive or nonimplant* or nonvaginal or noninvasive or external* or surface* or neuromuscular or wearable).tw.
14	12 or 13
15	Electric Stimulation Therapy/ or Electric Stimulation/
16	((electric* or electro*) adj4 (stimulat* or therap*)).tw.
17	electrotherap*.tw.
18	or/15-17
19	14 and 18
20	(NMES or NEES).tw.
21	((transcutaneous* or trans-cutaneous* or transdermal* or trans-dermal* or analgesic* cutaneous*) adj4 (electro* or electric* or stimulat* or therap*)).tw.
22	(electroanalgesia* or TENS or TNMES).tw.
23	or/20-22
24	19 or 23
25	11 and 24
26	INNOVO*.tw.
27	Neurotech vital*.tw.
28	or/25-27
29	animals/ not humans/
30	28 not 29

Appendix

The following table outlines the studies that are considered potentially relevant to the IP overview but were not included in the summary of the key evidence. It is by no means an exhaustive list of potentially relevant studies.

Additional papers identified

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in summary of key evidence section
Anderson CA, Omar MI, Campbell SE et al. Conservative management for postprostatectomy urinary incontinence. Cochrane Database of Systematic Reviews 2015, Issue 1. Art. No.: CD001843. DOI: 10.1002/14651858.CD001843.pub5. Accessed 18 November 2021	Systematic review (Cochrane) 50 trials (n=4,717)	Three small trials provided data and the meta-analysis suggested that electrical stimulation was better than control interventions in terms of less incontinence, regaining continence more quickly and better quality of life, at least in the short term up to 6 months. The quality of evidence was deemed to be moderate, however less information was available for the longer term.	Review included a range of conservative interventions. Electrical stimulation included anal electrical stimulation and sticky patch electrodes.
Berghmans B, Hendriks E, Bernards A et al. Electrical stimulation with non-implanted electrodes for urinary incontinence in men. Cochrane Database of Systematic Reviews 2013, Issue 6. Art. No.: CD001202. DOI: 10.1002/14651858.CD001202.pub5.	Systematic review (Cochrane) 6 trials n=544	There was some evidence that electrical stimulation enhanced the effect of pelvic floor muscle training in the short term but not after 6 months. There were, however, more adverse effects (pain or discomfort) with electrical stimulation.	Most of the studies used anal electrical stimulation.
Cruz E, Miller C, Zhang W et al. (2021) Does non-implanted electrical stimulation reduce	Systematic review 10 trials	Published trials evaluating the effect of non-implanted electrical stimulation on post-	The review focused on transcutaneous electrical nerve

post-stroke urinary or fecal incontinence? A systematic review with meta-analysis. International Journal of Stroke DOI: 10.1177/1747493021100 6301	n=894	stroke incontinence are few and heterogenous. Synthesised trials suggest that early and frequent treatment using electrical stimulation is probably more effective than sham or no treatment. Further trials measuring incontinence in an objective manner are needed.	stimulation and electro-acupuncture. NMES was described in 1 study, which is already included (Guo et al., 2018).
Demirturk F, Akbayrak T, Karakaya I et al. (2008) Interferential current versus biofeedback results in urinary stress incontinence. Swiss Medical Weekly 138: 317–21	Randomised controlled trial n=40 Follow up: end of treatment	All of the parameters improved after the treatments in each group ($p<0.05$) and both treatment modalities seemed to have similar effects on pad test (95% CI: -1.48 to -4.59), pelvic muscle strength (95% CI: -9.29 to -1.78) and quality of life (95% CI: -11.91 to -5.31) outcomes.	More recent studies are included.
Dumoulin C, Seaborne DE, Quirion-DeGirardi C et al. (1995) Pelvic-floor rehabilitation, Part 2: Pelvic-floor reeducation with interferential currents and exercise in the treatment of genuine stress incontinence in postpartum women--a cohort study. Physical Therapy 75: 1075–81	Cohort study n=8 Follow up=1 year	Five patients became continent, and 3 others improved. A follow-up survey 1 year later confirmed the consistency of these results.	Larger studies are included.
Hwang U-J, Kwon O-Y, Lee M-S (2020) Effects of surface electrical stimulation during sitting on pelvic floor muscle function and sexual function in women with stress urinary incontinence.	Randomised controlled trial n=32 Follow up: end of treatment (8 weeks)	Surface electrical stimulation during sitting can improve pelvic floor muscle function and sexual function in women with stress urinary incontinence.	Larger studies are included.

Obstetrics & Gynecology Science 63: 370–78			
Hwang U-J, Lee M-S, Jung S-H et al. (2020) Which pelvic floor muscle functions are associated with improved subjective and objective symptoms after 8 weeks of surface electrical stimulation in women with stress urinary incontinence? European Journal of Obstetrics, Gynecology, and Reproductive Biology 247: 16–21	Randomised controlled trial n=32 Follow up: end of treatment (8 weeks)	Surface electrical stimulation in a seated position improved both subjective and objective symptoms in females with stress urinary incontinence. Pelvic floor muscle power, the UDI-6 score, and the pad weight test result should be considered when developing intervention guidelines to improve the subjective and objective symptoms of females with stress urinary incontinence.	Larger studies are included.
Kilpatrick KA, Paton P, Subbarayan S et al. (2020) Non-pharmacological, non-surgical interventions for urinary incontinence in older persons: A systematic review of systematic reviews. The SENATOR project ONTOP series. Maturitas 133: 42–48	Systematic review 27 studies	There is sufficient evidence to warrant recommendation of group exercise therapy for stress incontinence and behavioural therapy for urgency, stress or mixed urinary incontinence in older women. Evidence was insufficient to recommend any other non-drug therapy.	Only 1 study on 'electrical stimulation' was included, which was not described in detail.
Maher RM, Caulfield B (2013) A novel externally applied neuromuscular stimulator for the treatment of stress urinary incontinence in women--"a pilot study. Neuromodulation: Journal of the International Neuromodulation Society 16: 590–94	Case series n=9 Follow up=end of treatment (8 weeks)	At week 8, patients reported a 98% decrease in leakage (p=0.0001). Changes noted in Incontinence Impact Questionnaire and Modified Oxford scores were statistically significant (p=0.0001 and p=0.0001). The device is noninvasive and can be used as a home treatment.	Larger and more recent studies are included.

Massari M, Desideri P, Menchinelli P et al. (2015) Urinary incontinence: Clinical observation on 30 patients undergoing treatment with F.R.E.M.S (Frequency Rhythmic Electrical Modulation System). Archivio italiano di urologia, andrologia : organo ufficiale [di] Societa italiana di ecografia urologica e nefrologica 87: 243–45	Case series n=30 Follow up=12 months	Electrodes were placed in bilateral paravertebral lumbosacral region (10 minutes at frequency of 110 Hz and automatic increase of 33% every 3 minutes, pulse duration 20µSec and variable voltage 70 to 250 Volts managed by the patient with sub-threshold remote control (+/-1 Volt); for further 10 minutes with a frequency of 420 Hz, pulse duration 10µSec and variable voltage 70 to 250 Volts managed by the patient) and in suprapubic region (10 minutes with variable frequency 1 to 100 Hz and variable duration 10 to 40 µSec (parameters managed by a software),and variable voltage up to 250 Volts managed by the patient). 93% of patients had a positive result, with either disappearance or improvement of symptoms.	Small case series with limited outcomes.
Okada N, Igawa Y, Ogawa A et al. (1998) Transcutaneous electrical stimulation of thigh muscles in the treatment of detrusor overactivity. British Journal of Urology 81: 560–4	Case series n=19 Follow up=3 months	In 11 of the 19 patients, the maximum cystometric capacity was increased by >50% of the pretreatment value; this happened in 8 of 14 of those with detrusor hyperreflexia and in 3 of 5 of those with idiopathic detrusor instability. In 6 of the 11 who had this response, there was a clinical improvement in their urinary incontinence and frequency for	Larger and more recent studies are included.

		several weeks to 3 months after the period of therapy. A second 14-day treatment was also effective in all 4 patients who had a repeat trial.	
Rai BP, Cody JD, Alhasso A et al. Anticholinergic drugs versus non-drug active therapies for non-neurogenic overactive bladder syndrome in adults. Cochrane Database of Systematic Reviews 2012, Issue 12. Art. No.: CD003193. DOI:10.1002/14651858.CD003193.pub4.	Systematic review (Cochrane) 23 trials (n=3,685)	Subjective improvement rates tended to favour the electrical stimulation group in 3 small trials (54% not improved with the anticholinergic versus 33% with electrical stimulation: risk ratio 0.64, 95% CI 1.15 to 2.34). However, this was statistically significant only for 1 type of stimulation, percutaneous posterior tibial nerve stimulation (risk ratio 2.21, 95% CI 1.13 to 4.33), and was not supported by statistically significant differences in improvement, urinary frequency, urgency, nocturia, incontinence episodes or quality of life.	Electrical stimulation included intravaginal electrical stimulation, transcutaneous electrical nerve stimulation, the Stoller Afferent Nerve Stimulation System neurom-odulation and percutaneous posterior tibial nerve stimulation.
Sciarra A, Viscuso P, Arditi A et al. (2021) A biofeedback-guided programme or pelvic floor muscle electric stimulation can improve early recovery of urinary continence after radical prostatectomy: A meta-analysis and systematic review. International Journal of Clinical Practice 75:e14208.	Systematic review 26 articles	Regarding non-invasive treatment of urinary incontinence secondary to radical prostatectomy, the addition of guided programs using biofeedback or pelvic floor electric stimulation improved continence recovery rate, particularly in the first 3-month interval, compared with using of pelvic floor muscle exercises alone.	11 articles included electrical stimulation, but most referred to anal stimulation None of them described electrical neuromuscular stimulation.

Stewart F, Berghmans B, Bø K et al. Electrical stimulation with non-implanted devices for stress urinary incontinence in women. Cochrane Database of Systematic Reviews 2017, Issue 12. Art. No.: CD012390. DOI: 10.1002/14651858.CD012390.pub2.	Systematic review (Cochrane) 56 trials (n=3,781)	The current evidence base indicated that electrical stimulation is probably more effective than no active or sham treatment, but it is not possible to say whether it is similar to pelvic floor muscle training or other active treatments in effectiveness or not. Overall, the quality of the evidence was too low to provide reliable results. Adverse effects were rare.	Most of the included trials used intravaginal electrical stimulation.
Stewart F, Gameiro LF, El Dib R et al. Electrical stimulation with non-implanted electrodes for overactive bladder in adults. Cochrane Database of Systematic Reviews 2016, Issue 12. Art. No.: CD010098. DOI: 10.1002/14651858.CD010098.pub4.	Systematic review (Cochrane) 63 trials (n=4,424)	Electrical stimulation shows promise in treating overactive bladder, compared to no active treatment, placebo or sham treatment, pelvic floor muscle training and drug treatment. It is possible that adding electrical stimulation to other treatments such as pelvic floor muscle training may be beneficial. The quality of the evidence base overall was low.	Most of the included trials used intravaginal or posterior tibial nerve electrical stimulation.
Su J, Wen J-G, Wang Q-W et al. (2006) Short-term effects of pelvic floor electrical stimulation on genuine stress urinary incontinence in women. Chinese Journal of Clinical Rehabilitation 10: 131–33	Case series n=50 Follow up: end of treatment (12 weeks)	Incontinence symptoms were cured in 24 patients (48%), improved in 21 patients (42%) and did not improve in 5 patients (10%). Comparison of subjective and objective index of urodynamics before and after treatment: the functional cystic capacity, Valsalva leak point pressure, maximal urethral pressure and maximal	Small case series with no follow up beyond the end of treatment.

		urethral closure pressure were statistically significantly larger and higher compared with before treatment ($p<0.05$). The total frequency of uresis, leakage and scores of ICI-Q-SF were statistically significantly lower compared with before treatment ($p<0.05$).	
Thomas LH, Coupe J, Cross LD et al. Interventions for treating urinary incontinence after stroke in adults. Cochrane Database of Systematic Reviews 2019, Issue 2. Art. No.: CD004462. DOI: 10.1002/14651858.CD004462.pub4.	Systematic review (Cochrane) 20 trials (n=1,338)	Physical therapies, such as transcutaneous electrical nerve stimulation, may reduce the average number of incontinent episodes in 24 hours and probably improves functional ability. The quality of the evidence was limited due to poor reporting of study details (particularly in the earlier studies) and the small number of study participants in most comparisons.	Although electrical stimulation was included, only trials that used transcutaneous electrical nerve stimulation or transcutaneous posterior tibial nerve stimulation were described.
Yokozuka M, Namima T, Nakagawa H et al. (2004) Effects and indications of sacral surface therapeutic electrical stimulation in refractory urinary incontinence. Clinical Rehabilitation 18: 899–907	Case series n=18	Based on subjective findings, sacral surface therapeutic electrical stimulation had therapeutic effects with 56% of patients more than ‘improved’ and 61% more than ‘slightly improved’. Based on objective findings, 44% of patients more than ‘improved’ and over 80% more than ‘slightly improved’.	Larger and more recent studies are included.