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Electrical stimulation with non-implanted electrodes for overactive bladder in adults (Review)

Stewart F, Gameiro LF, El Dib R, Gameiro MO, Kapoor A, Amaro JL

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[Intervention Review]

Electrical stimulation with non-implanted electrodes for overactive bladder in adults

Fiona Stewart¹, Luis F Gameiro², Regina El Dib³, Monica O Gameiro², Anil Kapoor⁴, Joao L Amaro⁵

¹Academic Urology Unit, University of Aberdeen, Aberdeen, UK. ²Rehabilitation Service, Universidade Estadual Paulista (UNESP), Botucatu, Brazil. ³Department of Anaesthesiology, Botucatu Medical School, UNESP - Univ Estadual Paulista, Botucatu, Brazil. ⁴Department of Surgery, McMaster University, Hamilton, Canada. ⁵Department of Urology, Medical School of Botucatu, Universidade Estadual Paulista (UNESP), Botucatu, Brazil

Contact address: Fiona Stewart, Academic Urology Unit, University of Aberdeen, Foresterhill, Aberdeen, Scotland, AB25 2ZD, UK. fiona.stewart@abdn.ac.uk.

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ABSTRACT

Background

Several options exist for managing overactive bladder (OAB), including electrical stimulation (ES) with non-implanted devices, conservative treatment and drugs. Electrical stimulation with non-implanted devices aims to inhibit contractions of the detrusor muscle, potentially reducing urinary frequency and urgency.

Objectives

To assess the effects of ES with non-implanted electrodes for OAB, with or without urgency urinary incontinence, compared with: placebo or any other active treatment; ES added to another intervention compared with the other intervention alone; different methods of ES compared with each other.

Search methods

We searched the Cochrane Incontinence Specialised Register, which contains trials identified from the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, MEDLINE In-Process, ClinicalTrials.gov, WHO ICTRP and handsearching of journals and conference proceedings (searched 10 December 2015). We searched the reference lists of relevant articles and contacted specialists in the field. We imposed no language restrictions.

Selection criteria

We included randomised or quasi-randomised controlled trials of ES with non-implanted devices compared with any other treatment for OAB in adults. Eligible trials included adults with OAB with or without urgency urinary incontinence (UUI). Trials whose participants had stress urinary incontinence (SUI) were excluded.

Data collection and analysis

Two review authors independently screened search results, extracted data from eligible trials and assessed risk of bias, using the Cochrane 'Risk of bias' tool.

Main results

We identified 63 eligible trials (4424 randomised participants). Forty-four trials did not report the primary outcomes of perception of cure or improvement in OAB. The majority of trials were deemed to be at low or unclear risk of selection and attrition bias and unclear risk of performance and detection bias. Lack of clarity with regard to risk of bias was largely due to poor reporting.

For perception of improvement in OAB symptoms, moderate-quality evidence indicated that ES was better than pelvic floor muscle training (PFMT) (risk ratio (RR) 1.60, 95% confidence interval (CI) 1.19 to 2.14; n = 195), drug treatment (RR 1.20, 95% 1.04 to 1.38; n = 439), and placebo or sham treatment (RR 2.26, 95% CI 1.85 to 2.77, n = 677) but it was unclear if ES was more effective than placebo/sham for urgency urinary incontinence (UUI) (RR 5.03, 95% CI 0.28 to 89.88; n = 242). Drug treatments included in the trials were oestrogen cream, oxybutynin, propantheline bromide, probanthine, solifenacin succinate, terodiline, tolterodine and trospium chloride.

Low- or very low-quality evidence suggested no evidence of a difference in perception of improvement of UUI when ES was compared to PFMT with or without biofeedback.

Low-quality evidence indicated that OAB symptoms were more likely to improve with ES than with no active treatment (RR 1.85, 95% CI 1.34 to 2.55; n = 121).

Low-quality evidence suggested participants receiving ES plus PFMT, compared to those receiving PFMT only, were more than twice as likely to report improvement in UUI (RR 2.82, 95% CI 1.44 to 5.52; n = 51).

There was inconclusive evidence, which was either low- or very low-quality, for OAB-related quality of life when ES was compared to no active treatment, placebo/sham or biofeedback-assisted PFMT, or when ES was added to PFMT compared to PFMT-only. There was very low-quality evidence from a single trial to suggest that ES may be better than PFMT in terms of OAB-related quality of life.

There was a lower risk of adverse effects with ES than tolterodine (RR 0.12, 95% CI 0.05 to 0.27; n = 200) (moderate-quality evidence) and oxybutynin (RR 0.11, 95% CI 0.01 to 0.84; n = 79) (low-quality evidence).

Due to the very low-quality evidence available, we could not be certain whether there were fewer adverse effects with ES compared to placebo/sham treatment, magnetic stimulation or solifenacin succinate. We were also very uncertain whether adding ES to PFMT or to drug therapy resulted in fewer adverse effects than PFMT or drug therapy alone. Nor could we tell if there was any difference in risk of adverse effects between different types of ES.

There was insufficient evidence to determine if one type of ES was more effective than another or if the benefits of ES persisted after the active treatment period stopped.

Authors' conclusions

Electrical stimulation shows promise in treating OAB, compared to no active treatment, placebo/sham treatment, PFMT and drug treatment. It is possible that adding ES to other treatments such as PFMT may be beneficial. However, the low quality of the evidence base overall means that we cannot have full confidence in these conclusions until adequately powered trials have been carried out, measuring subjective outcomes and adverse effects.

PLAIN LANGUAGE SUMMARY

Non-invasive electrical stimulation for overactive bladder in adults

Background

People with overactive bladder (OAB) have a frequent and compelling desire to urinate, which has a significant impact on quality of life. Many people with OAB also have urinary incontinence. OAB affects around 17% of the world's population and is particularly common in elderly people. Treatment for OAB includes pelvic floor muscle training, drug therapy and electrical stimulation.

Non-invasive electrical stimulation works by passing an electrical current through the bladder muscles, via a vaginal or anal probe, or through a fine needle inserted into the tibial nerve around the ankle. The current is intended to reduce (inhibit) contractions of the detrusor muscle (the bladder muscle which squeezes out urine); this should reduce the number of times a person will need to urinate. Invasive electrical stimulation involves implanting electrodes within the body and requires a surgical procedure.

Aim

We investigated whether electrical stimulation was better than no treatment at all or better than any other treatment available for OAB. We also investigated which type of electrical stimulation was better for OAB and whether or not electrical stimulation was safe.

Results

We identified 63 studies (4424 people altogether) comparing electrical stimulation to no treatment or any other available treatment. We found that electrical stimulation is probably better than sham electrical stimulation or pelvic floor muscle training at reducing the main symptoms of OAB.

Electrical stimulation may be better than no active treatment or drug treatment at reducing OAB symptoms but we are less certain about these results because the available evidence was less reliable.

Similarly, there was not enough evidence to tell if adding electrical stimulation to pelvic floor muscle training or to drug treatment helped to reduce OAB symptoms. Nor could we tell which type of electrical stimulation was better.

We did not find enough information to know whether or not electrical stimulation was safer than other treatments, or if one type of electrical stimulation was safer than others.

Many of the studies we identified did not report whether or not the treatment improved OAB symptoms or whether there were any side effects caused by any of the treatments.

Finally, we could not tell from the evidence whether or not any benefits of electrical stimulation continued after the course of electrical stimulation stopped.

The evidence in this review is current up to December 2015.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON *[Explanation]*

Electrical stimulation versus no active treatment						
Patient or population: Adults with overactive bladder (OAB) Setting: Hospitals (Brazil and UK) Intervention: Electrical stimulation Comparison: No active treatment						
Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	No. of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with no active treatment	Risk with electrical stimulation				
Participants cured or improved Follow-up: range 12 weeks to 12 months	Study population 424 per 1000	784 per 1000 (568 to 1000)	RR 1.85 (1.34 to 2.55)	121 (2 RCTs)	⊕⊕○○ LOW ¹²	
Participants with improvement in urgency urinary incontinence	See comment	See comment	Not estimable	(0 studies)	-	Not reported
OAB-related quality of life (higher score indicates better quality of life) Follow-up: range 5 weeks to 12 weeks	In one trial participants in the intervention group had lower ICI-Q scores (unclear if this was an important difference). In another no evidence of a difference was found between groups in of improvement in a range of QoL scores		-	148 (2 RCT)	⊕⊕○○ LOW ³	
Adverse effects	See comment	See comment	Not estimable	(0 studies)	-	Not reported

* **The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio; **OR:** Odds ratio

GRADE Working Group grades of evidence

High quality: We are very confident that the true effect lies close to that of the estimate of the effect

Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect

Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

¹ Downgraded one level due to serious risk of bias (high likelihood of selection bias).

² Downgraded one level due to serious imprecision (small number of trials, small sample sizes).

³ Downgraded two levels due to very serious imprecision (two trials with small sample sizes).

BACKGROUND

Description of the condition

Overactive bladder (OAB) is a chronic disorder with an overall prevalence in the adult population of over 10%, but that may exceed 40% in elderly groups (Irwin 2006). According to the International Continence Society, OAB is characterised by symptoms of urinary urgency (a strong compelling desire to urinate that is difficult to overcome), with or without urinary incontinence. If there is urinary incontinence accompanied by urgency, the leakage is called urgency urinary incontinence (UUI). Overactive bladder is usually accompanied by daytime frequency (increased need to urinate) and nocturia (waking during the night to urinate), but without urinary infection or other bladder pathologies (Abrams 2003). Overactive bladder with urinary incontinence is known as 'overactive bladder wet'; OAB without incontinence is known as 'overactive bladder dry'.

Overactive bladder has many potential causes, such as urinary tract infections, neurogenic diseases and pelvic organ prolapse. Urgency symptoms are often associated with involuntary contractions of the detrusor muscle in the bladder: this is termed detrusor overactivity if it is diagnosed using urodynamics. This overactivity can be related to neurogenic, myogenic, or idiopathic origins (Shaw 2011). However, currently its aetiology is unclear.

Urinary incontinence has many psychosocial implications. It appears that OAB has a greater psychological impact than stress urinary incontinence (SUI), with 60% of people with OAB reporting a history of depression compared with 14% of people with SUI (Zorn 1999).

Additionally, the financial impact of OAB can be substantial. Costs to health services and to patients are likely to be considerable given the relatively high prevalence of OAB, particularly in elderly people. The overall annual economic burden of OAB in the US in 2007 was estimated to be USD 65.9 billion, with the average annual per capita costs estimated to be USD 1925 (Gantz 2010). With the worldwide problems of increasingly constrained budgets and an aging population, it is imperative to ensure the efficient allocation of available resources; therefore value for money in OAB treatments must be considered.

Description of the intervention

Conservative management, such as bladder training (Wallace 2004) or pelvic floor muscle training, has been recommended as a first-line treatment for OAB (Abrams 2003).

The main type of medical treatment for OAB is pharmacotherapy with anticholinergics, which have proven to be effective in several randomised controlled trials (RCTs) (Madhuvrata 2012). However, common side effects such as dry mouth and constipation limit long-term compliance, with discontinuation rates of 70%

to 90% within one year (D'Souza 2008). Intravesical botulinum toxin injections may be an effective and safe option to treat refractory OAB (Duthie 2011); in the UK, bladder wall injections with botulinum toxin A are recommended for women with OAB caused by proven detrusor overactivity if conservative or drug treatments have failed (NICE 2013). This is considered to be a surgical intervention in this review.

In people for whom conservative or drug treatment is not sufficient, neuromodulation is an alternative. It is thought that neuromodulation with electrical stimulation (ES) can target specific nerves in the sacral plexus that control pelvic floor function.

ES can be used to treat OAB via different routes, such as implantable or internal (sacral neuromodulation) and non-implantable external electrodes. Stimulation with non-implanted electrodes can be delivered invasively (percutaneous stimulation), semi-invasively (typically vaginal or anal probes) or non-invasively (transcutaneous stimulation).

ES can be used on its own or in association with pelvic floor muscle training, often indicated in SUI and OAB. There is currently little consensus regarding the optimum treatment regimen, the number and duration of sessions and the parameters used, such as electrical frequency and pulse width.

This review includes non-implanted electrodes only; implanted devices are included in another Cochrane systematic review (Herbison 2009).

Routes of administration

Intravaginal electrical stimulation

Intravaginal ES for treating urinary incontinence was first reported in the literature in the 1960s (Cadwell 1963). Subsequently, it has been shown to achieve satisfactory results with frequencies below 12 Hertz (Hz) stimulating the pudendal nerve, which is thought to inhibit the detrusor muscle, reduce involuntary contractions and, consequently, reduce the number of micturitions (Messelink 1999). ES also works in a passive way, helping people with OAB become conscious of their perineal (pelvic floor) muscle contractions and this may, in turn, help to inhibit involuntary detrusor contractions (Amaro 2003).

The contraindications to intravaginal ES are pregnancy, vaginal infection or lesion, a reduced perception of vaginal sensation, menstruation, and metallic implants (Richardson 1996).

Rectal (anal) electrical stimulation

Transcutaneous electrical nerve stimulation (TENS) delivers an electrical current through an electrode placed in the ischioanal area. Electrodes inserted in the rectal canal may inhibit detrusor contractions through contact with the pudendal nerve afferent fibres and thus may be effective in the treatment of UUI and OAB.

Posterior tibial nerve stimulation

Percutaneous tibial nerve stimulation is a form of neuromodulation that delivers retrograde stimulation to the sacral nerve plexus via a needle electrode inserted into the ankle, cephalad to the medial malleolus, an anatomical area recognised as the bladder centre. Transcutaneous tibial nerve stimulation is less invasive than percutaneous stimulation and can be delivered over the peroneal region of the ankle through surface electrodes (ICI 2013).

How the intervention might work

ES is thought to inhibit detrusor contractions, thus decreasing the number of micturitions and potentially increasing bladder capacity (Wang 2006). Electrodes can be located in the vaginal or rectal canals in such a way as to obtain direct contact with a significant quantity of afferent nerve fibres of the pudendal nerve. This stimulation of the pudendal nerve activates the skeletal pelvic floor muscles and inhibits detrusor contraction. Partial or total innervation of the pudendal nerve is necessary so that nerve stimulation can occur (Messelink 1999). The anal electrode can be used for men to stimulate the pudendal nerve, or in women where the vaginal approach is contraindicated.

There are two main mechanisms whereby ES is thought to work.

- ES in the form of neurostimulation aims to stimulate motor efferent fibres of the pudendal nerve, which elicits a direct response from the effector organ, for instance a contraction of the pelvic floor muscles (Fall 1991; Scheepens 2003).
- ES in the form of neuromodulation aims to remodel reflex loops, for instance the detrusor inhibition reflex, by stimulating afferent nerve fibres of the pudendal nerve that influence these reflex loops via the spinal cord (Vodusek 1986; Weil 2000).

The different sites for non-implanted ES, for instance direct intravaginal stimulation or peripheral transcutaneous tibial nerve stimulation, may involve different mechanisms and therefore may have different degrees of effectiveness.

Why it is important to do this review

Numerous treatment options exist for OAB, including behavioural therapies such as pelvic floor muscle rehabilitation, bladder training, and dietary modification, as well as pharmacological therapy and neuromodulation. Overall, behavioural therapies are considered the mainstay of treatment for urinary incontinence. It is known that OAB can be improved through behavioural therapy or drug treatment, but it is not known whether non-invasive ES achieves better clinical outcomes. This review aims to present an overview of current evidence related to ES in the treatment of OAB.

This systematic review aims to investigate the effects of non-implanted ES in people with OAB with or without urgency incontinence. It also aims to compare specific subgroups to investigate

whether ES might be more beneficial for some populations than for others.

OBJECTIVES

To assess the effects of electrical stimulation (ES) with non-implanted electrodes for OAB, with or without urgency urinary incontinence (UUI), compared with: placebo or any other active treatment; ES added to another intervention compared with the other intervention alone; different methods of ES compared with each other.

METHODS

Criteria for considering studies for this review

Types of studies

We included randomised controlled trials (RCTs), quasi-RCTs (RCTs in which allocation to treatment was based on methods such as alternate medical records, date of birth, or other predictable methods) and randomised cross-over trials.

Types of participants

Eligible studies included adults (≥ 18 years old, or according to study authors' definitions of adult) with either of the following:

- symptomatic diagnosis of overactive bladder (OAB), urgency urinary incontinence (UUI), or mixed urinary incontinence;
- urodynamic diagnosis of detrusor overactivity in addition to OAB symptoms (urgency, frequency or episodes of urgency incontinence).

Studies including participants with stress urinary incontinence (SUI), with or without OAB symptoms were included if data were reported separately for SUI and participants with OAB, or if the majority ($> 50\%$) of the population had OAB/UUI-predominant symptoms.

Types of interventions

Eligible comparators were any intervention intended to decrease urinary frequency and included placebo, sham treatment, conservative treatment (including complementary therapies), drugs and surgery. We also included studies comparing different electrical

stimulation (ES) methods with each other. There were no restrictions by type of device, stimulation parameters (such as continuous, interrupted, or duration of stimulation), duration of treatment, route of administration (e.g. vaginal, rectal, skin, pretibial area), or other similar factors. We excluded trials of different combinations of treatments even if one of those was ES, where it was not possible to identify the effect of this treatment alone (e.g. ES plus another treatment versus ES plus other combined treatments).

We investigated the following comparisons:

1. ES versus no active treatment
2. ES versus placebo or sham treatment
3. ES versus other conservative treatments (e.g. bladder training, pelvic floor muscle training, biofeedback, magnetic stimulation)
4. ES versus drug therapy (e.g. anticholinergics)
5. ES versus surgery (including botulinum toxin)
6. ES plus another treatment versus other treatment alone
7. One type of electrical stimulation versus another.

Types of outcome measures

We considered the following outcomes. Where outcome data were reported at more than one follow-up point, we extracted the data from the end of treatment and from the longest available follow-up period.

Primary outcomes

- Perception of cure (number of participants without OAB symptoms; number of participants without self-reported UUI)
- Perception of improvement (number of participants with improvement in OAB symptoms; number of participants with improvement in self-reported UUI)
- Condition-related quality-of-life measures (however defined by authors or by any validated measurement scales such as the International Consultation on Incontinence Questionnaire (ICIQ))

Secondary outcomes

- Quantification of symptoms
 - Number of incontinence episodes (per 24 hours)
 - Number of urgency episodes (per 24 hours)
 - Number of micturitions (per 24 hours)
 - Number of nocturia episodes (per night)
 - Number of pads used per 24 hours
- Economic data
 - Costs of interventions
 - Cost-effectiveness of interventions
 - Resource implications
- Procedure outcome measures

- Duration of procedure
- Length of hospital stay
- Time to return to normal activity level

- Adverse effects
 - Skin damage
 - Pain or discomfort
 - Vascular, visceral or nerve injury
 - Voiding dysfunction
 - Other complications

We also included other outcomes that were not pre-specified but were deemed important during the course of data analysis.

Grading of Recommendations Assessment, Development and Evaluation (GRADE) outcomes

We included the following outcomes in 'Summary of findings' tables (Guyatt 2008).

- Number of participants with improvement in OAB symptoms or urgency symptoms
- Number of participants with improvement in self-reported UUI
- OAB-related quality of life
- Number of participants with adverse effects (pain or discomfort due to treatment)
- Cost-effectiveness of interventions

Search methods for identification of studies

We did not impose any restrictions, for example language or publication status, on the searches described below.

Electronic searches

This review drew on the search strategy developed for Cochrane Incontinence. We identified relevant trials from the Cochrane Incontinence Specialised Trials Register. For more details of the search methods used to build the Specialised Register please see the Group's [module](#) in the Cochrane Library. The Register contains trials identified from the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, MEDLINE In-Process, [ClinicalTrials.gov](#), WHO International Clinical Trials Registry Platform (WHO ICTRP), [UK Clinical Research Network Portfolio](#) and handsearching of journals and conference proceedings. Most of the trials in the Cochrane Incontinence Specialised Register are also contained in CENTRAL. The date of the last search was 10 December 2015. The terms used to search the Cochrane Incontinence Specialised Register are given in [Appendix 1](#).

Some of the review authors (OLFG, RE, MOG, AK, JLA) also searched the following databases; the search terms used are given in [Appendix 1](#)

- PubMed (inception to December 2015) was searched on 12 December 2015;
- CENTRAL (*The Cochrane Library* 2015, Issue 12) was searched on 12 December 2015;
- Embase on OvidSP (covering from 1980 onwards) and the Latin-American and Caribbean Center on Health Sciences Information (LILACS) (on the Virtual Health Library/Bireme) (covering from 1982 to December 2015) were both searched on 12 December 2015. The highly sensitive Embase and LILACS strategies for identification of RCTs (Castro 1997; Castro 1999; Lefebvre 2011) were combined with search terms relating to the condition and interventions;
- Information about ongoing clinical trials was sought by searching the clinical trials registration sites ClinicalTrials.gov and WHO ICTRP on 12 December 2015.

Searching other resources

Reference lists

The review authors scrutinised the reference lists of the identified relevant studies for additional citations.

Personal contact

We consulted clinical specialists and contacted authors of included trials where appropriate to obtain unpublished data.

Data collection and analysis

Selection of studies

Two review authors independently screened the trials identified by the literature search. We resolved any disagreements by consulting a third review author.

Data extraction and management

One review author extracted data, which was checked by a second reviewer, with discrepancies resolved by discussion. We used a pre-standardised data extraction form to extract data pertaining to study characteristics (design, methods of randomisation), participants, interventions and outcomes.

Assessment of risk of bias in included studies

Two review authors independently assessed risk of bias in included trials using the Cochrane tool for assessing risk of bias (Higgins 2011), considering the following four domains: random sequence generation, allocation concealment, blinding, and incomplete outcome data. We resolved any disagreements by consulting a third review author.

Measures of treatment effect

We analysed included trial data as described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2011).

Binary outcomes

For dichotomous data, we calculated risk ratios (RRs) with 95% confidence intervals (CIs).

Continuous outcomes

For continuous data, we have presented mean differences (MDs) with 95% CIs.

Unit of analysis issues

The unit of analysis is each participant recruited into the trials. We analysed studies with non-standard designs as described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2011). We analysed studies with multiple treatment groups by treating each pair of arms as a separate comparison, as appropriate. For randomised cross-over studies we used data from the first period of treatment only.

Dealing with missing data

We analysed data on an intention-to-treat (ITT) basis, as far as possible, whereby all participants must be analysed according to the groups to which they were randomised. Where participants were excluded after allocation or withdrew from the trial, we have reported any details provided in full. Where data from randomised cross-over trials were incomplete we have included data from the first period of randomisation only.

We made all reasonable attempts to contact study authors for clarification of missing data. Where trials reported mean values without standard deviations (SDs) but with P values or 95% CIs, we used Review Manager's (RevMan) calculator to estimate the SDs (RevMan 2014). Where trials reported mean values only, we assumed the outcome to have a SD equal to the highest SD from the other trials within the same analysis.

Assessment of heterogeneity

We assessed clinical heterogeneity by examination of the study details and tested for statistical heterogeneity between trial results using the Chi² test (Deeks 2011) and the I² statistic (Higgins 2003), using the following I² values:

- less than 30% heterogeneity may not be important;
- 30% to 50% may represent moderate heterogeneity;
- more than 50% may represent substantial or considerable heterogeneity.

Assessment of reporting biases

We intended to assess the likelihood of potential publication bias using funnel plots but insufficient data were available.

Data synthesis

We used Cochrane's statistical software, Review Manager 5 (RevMan) (RevMan 2014), for data analysis. We used the fixed-effect model to analyse data. Where we identified significant heterogeneity (for example I^2 higher than 50%), we computed pooled estimates of the treatment effect for each outcome under a random-effects model (with two or more studies).

Where outcomes were reported which were similar to, but not precisely the same, as pre-specified ones, we used 'surrogate' outcomes to substitute for missing data. For example, if a trial reported episodes of urinary incontinence without specifying the type of incontinence (e.g. SUI or UUI), we used the data as a substitute for UUI. Similarly, we used 'improvement in urgency symptoms' as a substitute for 'improvement in OAB symptoms'. Finally, if a subjective outcome (such as OAB symptoms) was reported as combined with an objective outcome (such as detrusor overactivity) without reporting them separately, we used that outcome as a surrogate for the subjective outcome.

In comparing ES to drug therapy we have presented subgroups for each drug but this is for presentation purposes only and is not intended to act as an indirect comparison between drugs. When comparing ES to drug therapy, in terms of adverse effects, we did not use a pooled estimate of effect because of the variation between drugs in the range of possible side effects.

Subgroup analysis and investigation of heterogeneity

In the case of substantial heterogeneity ($I^2 > 50\%$), we investigated the causes of heterogeneity and, where data permitted, carried out the following subgroup analyses:

- participants with idiopathic OAB versus those with neurogenic OAB;
- approaches of electrodes (transcutaneous (e.g. perineal skin, sacral, posterior pretibial nerve), endocavitary (vaginal, rectal, urethral), and percutaneous (posterior pretibial nerve)).

In some cases, we have presented forest plots with subgroups for illustrative purposes only, for instance in comparison 2 (electrical stimulation compared to other conservative treatments), we

wanted to demonstrate the various comparators in the trials so we conveyed this information in the names of the subgroups. Similarly, we used the same approach in comparison 4 (electrical stimulation plus another treatment compared to the other treatment alone), to demonstrate the various other treatments.

Sensitivity analysis

We intended to perform a sensitivity analysis comparing trials with low risk of selection bias to those with high risk of bias but there were insufficient numbers of eligible trials.

'Summary of findings' tables

We applied the principles of the GRADE system to assess the quality of the body of evidence associated with specific outcomes (perception of cure, perception of improvement and OAB-related quality of life) (Guyatt 2008). The GRADE approach appraises the quality of a body of evidence based on the extent to which one can be confident that an estimate of effect or association reflects the item being assessed. The quality of a body of evidence considers within-study risk of bias (methodological quality), the directness of the evidence, heterogeneity of the data, precision of effect estimates, and risk of publication bias. We constructed 'Summary of findings' tables using the GRADEpro GDT software (GRADEpro GDT 2015).

RESULTS

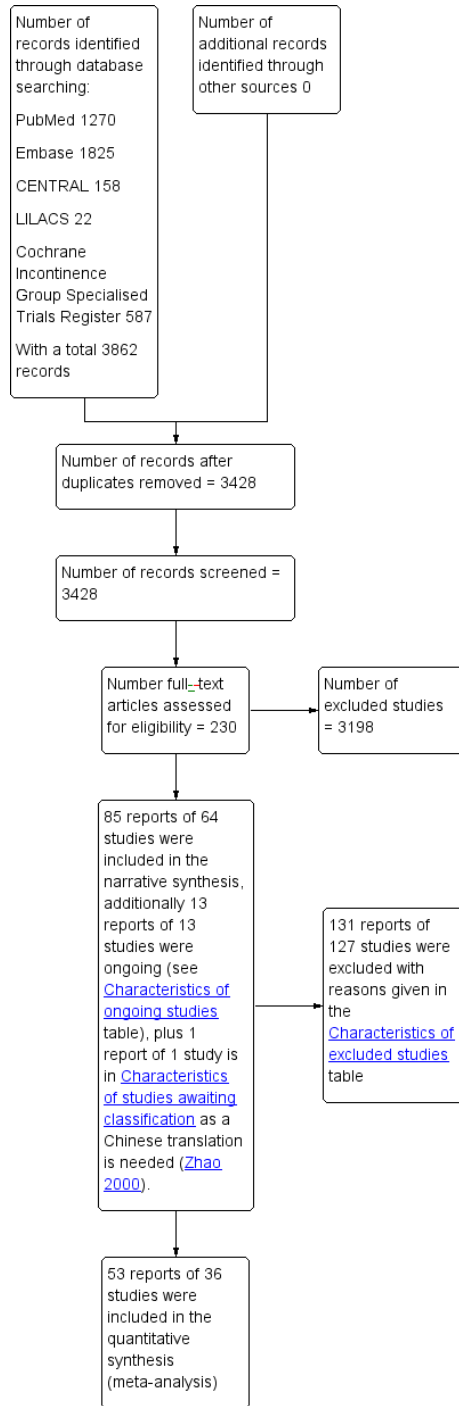
Description of studies

See: [Characteristics of included studies](#); [Characteristics of excluded studies](#).

Results of the search

The search strategy identified 3862 records; after removal of duplicate references there was a total of 3428 titles and abstracts to screen. Following assessment of 230 full-text articles, we considered 84 reports of 63 studies that met the minimal methodological requirements for inclusion in this review. [Figure 1](#) details the screening process.

Figure 1. PRISMA study flow diagram



Thirteen reports of 13 ongoing studies were identified and have been added to the list of ongoing studies ([NTR2192](#); [NCT01783392](#); [NCT02456441](#); [NCT02583529](#); [NCT02377765](#); [NCT01940367](#); [NCT02582151](#); [NCT01464372](#); [NCT01912885](#); [NCT02452593](#); [NCT02110680](#); [NCT02311634](#); [NCT02511717](#)) (see: [Characteristics of ongoing studies](#)).

Included studies

The individual trials are described in the [Characteristics of included studies](#) table.

Sixty-three trials (84 reports) met the inclusion criteria and were included in this review. A total of 4224 participants were randomised across the included trials.

Design

All but five of the included studies were reported as RCTs. We included three randomised cross-over trials ([Gonzalez 2015](#); [Soomro 2001](#); [Vecchioli-Scaldazza 2013](#)) and two quasi-RCTs ([Svihra 2002](#); [Wise 1992](#)).

Sample size

Thirty-seven of the included studies did not report any details relating to sample size calculation. Sample sizes ranged from 22 to 315 (median 51).

Setting

The trials took place in a variety of countries:

- 12 trials took place in Brazil ([Alves 2015](#); [Amaro 2006](#); [Arruda 2008](#); [Barroso 2002](#); [Boaretto 2011](#); [Bellette 2009](#); [Marques 2008](#); [Monteiro 2014](#); [Schmidt 2009](#); [Schreiner 2010](#); [Schreiner 2014](#); [Souto 2014](#));
- 10 in the UK ([Booth 2013](#); [Monga 2011](#); [Oldham 2013](#); [Seth 2014](#); [Shepherd 1984](#); [Shepherd 1985](#); [Slovak 2015](#); [Vohra 2002](#); [Wise 1992](#); [Wise 1993](#));
- nine in the USA ([Brubaker 1997](#); [Firra 2013](#); [Kennelly 2011](#); [Lobel 1998](#); [Peters 2009](#); [Peters 2010](#); [Phillips 2012](#); [Smith 1996](#); [Sotelo 2011](#));
- three each in Australia ([Bower 1998](#); [Lo 2003](#); [Soomro 2001](#)), Italy ([Finazzi-Agrò 2005](#); [Finazzi-Agrò 2010](#); [Vecchioli-Scaldazza 2013](#)) and Taiwan ([Wang 2004](#); [Wang 2006](#); [Wang 2009](#));
- two each in Chile ([Gonzalez 2015](#); [Manriquez 2013](#)), China ([Chen 2015](#); [Lin 2004](#)), Japan ([Yamanishi 2000a](#); [Yamanishi 2000b](#)) the Netherlands ([Berghmans 2002](#); [Spruijt 2003](#));

- one each in Belgium ([Gaspard 2014](#)), Egypt ([Abdelbary 2015](#)), Finland ([Vahtera 1997](#)), Iran ([Eftekhari 2014](#)), Russia ([Kosilov 2013](#)), Slovakia ([Svihra 2002](#)), Spain ([Olmo Carmona 2013](#)) and Sweden ([Franzén 2010](#)); and Turkey ([Sancaktar 2010](#))
- one in Austria and Germany ([Preyer 2015](#)).

Five studies did not report the country or any details on study setting ([Aaronson 1995](#); [Lima 2011](#); [Orhan 2015](#); [Preyer 2007](#); [Walsh 2001](#)).

Very few details were reported regarding study settings; exceptions were one trial carried out in residential care homes and sheltered accommodation ([Booth 2013](#)) and trials investigating types of ES suitable for home or portable use ([Barroso 2002](#); [Kennelly 2011](#); [Monga 2011](#); [Oldham 2013](#); [Phillips 2012](#); [Seth 2014](#); [Shepherd 1985](#); [Soomro 2001](#); [Sotelo 2011](#); [Wise 1992](#); [Wise 1993](#)).

Participants

The trials included a variety of participant groups.

Sex

Fourteen trials were open to men and women ([Booth 2013](#); [Olmo Carmona 2013](#); [Gaspard 2014](#); [Kennelly 2011](#); [Monga 2011](#); [Peters 2009](#); [Peters 2010](#); [Phillips 2012](#); [Slovak 2015](#); [Soomro 2001](#); [Vahtera 1997](#); [Walsh 2001](#); [Yamanishi 2000a](#); [Yamanishi 2000b](#)), one was open only to men ([Monteiro 2014](#)), and six did not report the participants' sex ([Gonzalez 2015](#); [Lin 2004](#); [Orhan 2015](#); [Seth 2014](#); [Sotelo 2011](#); [Vohra 2002](#)). All other trials were open to women only.

Age

One trial included only participants over 65 years ([Booth 2013](#)). Two trials included only participants over 60 years ([Alves 2015](#); [Schreiner 2014](#)) and another imposed a lower age limit of 40 ([Abdelbary 2015](#)). The [Olmo Carmona 2013](#) trial included participants aged 45 to 75 (mean 60 years). Fourteen trials did not report participants' mean age ([Alves 2015](#); [Lima 2011](#); [Manriquez 2013](#); [Marques 2008](#); [Monga 2011](#); [Orhan 2015](#); [Phillips 2012](#); [Preyer 2015](#); [Seth 2014](#); [Shepherd 1984](#); [Shepherd 1985](#); [Wang 2006](#); [Wise 1992](#); [Wise 1993](#)). Across the remaining trials, the mean age of participants in the trials ranged from 46 to 70 years.

Diagnosis

The participants had a variety of diagnoses of the causes of their overactive bladder (OAB).

- Fourteen trials based their inclusion criteria on urodynamic diagnosis ([Aaronson 1995](#); [Arruda 2008](#); [Berghmans 2002](#);

Bower 1998; Brubaker 1997; Finazzi-Agrò 2010; Lobel 1998; Shepherd 1985; Smith 1996; Walsh 2001; Wise 1992; Wise 1993; Yamanishi 2000a; Yamanishi 2000b).

- Six trials included only participants with neurogenic OAB or detrusor overactivity (Chen 2015; Eftekhar 2014; Gaspard 2014; Monteiro 2014; Seth 2014; Vahtera 1997).

- All other trials reported inclusion criteria based on symptomatic diagnosis of OAB, urgency urinary incontinence (UUI), or any kind of incontinence or bladder dysfunction.

Eleven trials included participants with mixed urinary incontinence (MUI and stress urinary incontinence (SUI)) (Barroso 2002; Booth 2013; Brubaker 1997; Firra 2013; Lo 2003; Oldham 2013; Schmidt 2009; Shepherd 1984; Shepherd 1985; Smith 1996; Spruijt 2003). All other trials included participants with OAB and UUI only.

Duration of trials

Treatment duration ranged from a single one-off session to four months. Fifteen trials followed up participants beyond the end of the treatment period (Abdelbary 2015; Amaro 2006; Arruda 2008; Barroso 2002; Gaspard 2014; Kosilov 2013; Lobel 1998; Monteiro 2014; Peters 2010; Schmidt 2009; Schreiner 2010; Slovak 2015; Souto 2014; Vahtera 1997; Vecchioli-Scaldazza 2013). The duration of post-treatment follow-up ranged from one month to two years. Four trials did not report treatment duration or follow-up.

Types of interventions

The parameters and components of the active electrical stimulation (ES) interventions varied widely and are summarised in Table 1.

Control/comparator interventions included the following.

- No active treatment (Berghmans 2002; Marques 2008; Monteiro 2014; Oldham 2013; Slovak 2015; Svihra 2002; Vahtera 1997)
- Sham ES (Amaro 2006; Barroso 2002; Bellette 2009; Booth 2013; Bower 1998; Brubaker 1997; Finazzi-Agrò 2010; Kennelly 2011; Peters 2010; Shepherd 1984; Shepherd 1985; Vohra 2002; Walsh 2001; Yamanishi 2000a)
- Placebo (Kosilov 2013; Wang 2006; Wang 2009)
- Pelvic floor muscle training (PFMT) (Arruda 2008; Berghmans 2002; Boaretto 2011; Firra 2013; Gaspard 2014; Lima 2011; Lo 2003; Schmidt 2009; Schreiner 2010; Spruijt 2003; Wang 2004)
- PFMT plus biofeedback (Gaspard 2014; Schmidt 2009; Wang 2004)
- Bladder training and PFMT (Schreiner 2014)
- Behavioural therapy (Gonzalez 2015)
- Electro-acupuncture (Olmo Carmona 2013)
- Laseropuncture (Kosilov 2013)

- Functional magnetic stimulation (Yamanishi 2000b)
- Drug treatment (oestrogen cream, oxybutynin, propantheline bromide, probanthine, solifenacin succinate, terodiline, tolterodine and tiroprium chloride) (Aaronson 1995; Abdelbary 2015; Arruda 2008; Boaretto 2011; Chen 2015; Franzén 2010; Kosilov 2013; Lin 2004; Manriquez 2013; Orhan 2015; Peters 2009; Preyer 2007; Preyer 2015; Sancaktar 2010; Smith 1996; Soomro 2001; Souto 2014; Svihra 2002; Vecchioli-Scaldazza 2013; Wang 2006; Wang 2006; Wang 2009; Wise 1992; Wise 1993)
- Different ES regimens (Alves 2015; Lobel 1998; Monga 2011; Phillips 2012; Seth 2014; Slovak 2015; Sotelo 2011)

In one trial (Marques 2008) it was unclear whether the comparator was no active treatment or sham treatment; the description was “the same protocol but without electrical stimulation.”

Types of outcomes

Nineteen trials reported the primary outcomes of perception of cure or improvement of OAB symptoms (Aaronson 1995; Bellette 2009; Booth 2013; Kennelly 2011; Lin 2004; Lo 2003; Lobel 1998; Monteiro 2014; Peters 2009; Peters 2010; Schmidt 2009; Shepherd 1985; Smith 1996; Soomro 2001; Spruijt 2003; Vohra 2002; Wang 2004; Wang 2006; Wang 2009).

A validated measure of quality of life (QoL) was reported in 22 trials (Alves 2015; Bellette 2009; Olmo Carmona 2013; Chen 2015; Finazzi-Agrò 2010; Firra 2013; Gaspard 2014; Gonzalez 2015; Oldham 2013; Orhan 2015; Peters 2010; Phillips 2012; Sancaktar 2010; Schmidt 2009; Schreiner 2010; Schreiner 2014; Seth 2014; Souto 2014; Svihra 2002; Vecchioli-Scaldazza 2013; Wang 2004; Wang 2009). Two trials reported QoL, but did not state the instrument used (Abdelbary 2015; Preyer 2007), and another trial used an in-house QoL instrument (Yamanishi 2000a). Thirteen trials did not report any of the primary outcomes (Berghmans 2002; Bower 1998; Eftekhar 2014; Kosilov 2013; Manriquez 2013; Monga 2011; Preyer 2015; Sancaktar 2010; Slovak 2015; Sotelo 2011; Vahtera 1997; Wise 1993; Yamanishi 2000b).

Five trials reported urodynamic outcomes only (Berghmans 2002; Bower 1998; Vahtera 1997; Walsh 2001; Yamanishi 2000b).

Twenty trials reported data relating to adverse effects (Chen 2015; Finazzi-Agrò 2005; Franzén 2010; Gaspard 2014; Kennelly 2011; Lin 2004; Lobel 1998; Oldham 2013; Peters 2010; Phillips 2012; Preyer 2007; Preyer 2015; Sancaktar 2010; Schreiner 2010; Soomro 2001; Sotelo 2011; Svihra 2002; Wise 1993; Yamanishi 2000a; Yamanishi 2000b).

None of the trials reported any data relating to procedure outcome measures.

Excluded studies

After full-text screening, we excluded 132 reports of 128 studies from the review. The main reasons for exclusion were ineligible study design (non-RCTs), ineligible population (participants did not have OAB or UUI), and ineligible interventions such as sacral neuromodulation with implanted devices or magnetic stimulation. See the table 'Characteristics of excluded studies' for full details of the excluded studies.

Studies awaiting classification

One report of one study is awaiting translation (Zhao 2000).

Ongoing studies

We identified 13 reports of 13 ongoing trials that met our inclusion criteria (Characteristics of ongoing studies).

The following comparisons are being investigated in the ongoing trials.

- ES versus sham ES (NCT02456441; NCT02583529; NCT01464372; NCT02582151; NCT02110680; NCT02511717)
- ES versus conservative treatment (bladder training; NTR2192; PFMT: NCT02452593)
- Different types of ES (NCT01783392; NCT02377765; NCT01940367; NCT01912885; NCT02311634)

Risk of bias in included studies

See Figure 2 Figure 3.

Figure 2. 'Risk of bias' graph: review authors' judgements about each risk of bias item presented as percentages across all included studies

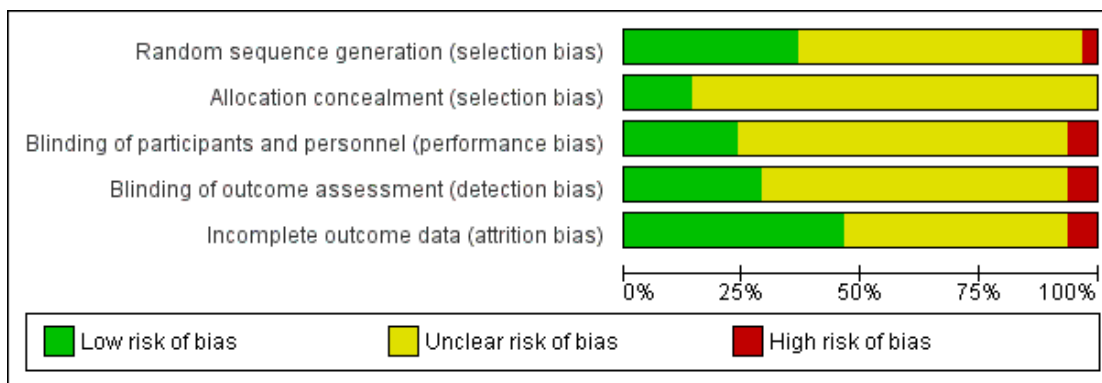


Figure 3. 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included study



Allocation

Random sequence generation

Two trials were judged to be at high risk of bias for random sequence generation (Monteiro 2014; Svihra 2002) because their methods of sequence generation did not appear to be truly random. Twenty-three trials were judged to be at low risk of bias for randomisation (Abdelbary 2015; Arruda 2008; Barroso 2002; Bellette 2009; Berghmans 2002; Booth 2013; Brubaker 1997; Olmo Carmona 2013; Eftekhar 2014; Finazzi-Agrò 2010; Firra 2013; Franzén 2010; Gonzalez 2015; Oldham 2013; Peters 2009; Preyer 2015; Sancaktar 2010; Schreiner 2010; Slovak 2015; Souto 2014; Spruijt 2003; Vohra 2002; Wang 2009). The remaining trials did not report their methods in sufficient detail to judge whether allocation to groups was fully randomised and therefore were at unclear risk of bias.

Allocation concealment

Nine trials reported adequate methods of concealment of allocation and so were at low risk of bias (Berghmans 2002; Olmo Carmona 2013; Firra 2013; Franzén 2010; Preyer 2015; Shepherd 1984; Slovak 2015; Wang 2004; Wang 2006), none were judged to be at high risk and the remainder did not report sufficient detail regarding their methods of allocation concealment and we therefore judged them to have an unclear risk of bias.

Blinding

Blinding of participants and personnel (performance bias)

Four trials (Arruda 2008; Bellette 2009; Eftekhar 2014; Preyer 2015) were judged to be at high risk of performance bias because treatment was carried out by personnel who were aware of treatment group allocation, which may have influenced their treatment methods.

Fifteen trials had adequate blinding methods to be judged at low risk of performance bias (Alves 2015; Amaro 2006; Barroso 2002; Berghmans 2002; Booth 2013; Bower 1998; Brubaker 1997; Finazzi-Agrò 2010; Kennelly 2011; Peters 2010; Shepherd 1985; Slovak 2015; Wang 2006; Wang 2009; Yamanishi 2000a) and the remainder were unclear.

For some comparisons, blinding of participants would not be possible, for instance ES versus drug treatment, versus surgery or versus conservative treatment. Trials investigating those comparisons were judged to be at unclear risk of performance bias because knowledge of the treatment received may have had an influence on self-reported outcomes but there was no means of avoiding it.

Blinding of outcome assessment (detection bias)

Four trials (Firra 2013; Bellette 2009; Eftekhar 2014; Preyer 2015) were at high risk of detection bias because the outcome assessors were not blinded to group allocation.

Eighteen trials were judged to be at low risk of detection bias (Alves 2015; Amaro 2006; Arruda 2008; Barroso 2002; Berghmans 2002; Brubaker 1997; Olmo Carmona 2013; Finazzi-Agrò 2010; Gaspard 2014; Kennelly 2011; Lo 2003; Oldham 2013; Schmidt 2009; Shepherd 1984; Slovak 2015; Vecchioli-Scaldazza 2013; Wang 2004; Wang 2006) and the remainder were unclear.

Incomplete outcome data

Four trials were at high risk of attrition bias.

- Gonzalez 2015 and Seth 2014 reported differential attrition with no adequate explanation and did not report whether the analysis included all participants who were randomised.
- Schreiner 2014 reported 12 month follow-up data for a proportion of the intervention group and no 12 month data for the comparator group.
- Wise 1993 experienced differential withdrawal for reasons attributable to the comparator.

Twenty-eight trials were judged to be at low risk of attrition bias (Alves 2015; Arruda 2008; Bellette 2009; Berghmans 2002; Booth 2013; Olmo Carmona 2013; Chen 2015; Finazzi-Agrò 2010; Franzén 2010; Gaspard 2014; Kennelly 2011; Lin 2004; Lobel 1998; Monteiro 2014; Peters 2009; Peters 2010; Preyer 2007; Preyer 2015; Schmidt 2009; Schreiner 2010; Spruijt 2003; Vecchioli-Scaldazza 2013; Vohra 2002; Walsh 2001; Wang 2004; Wang 2009; Yamanishi 2000a; Yamanishi 2000b) and the remainder were unclear.

Effects of interventions

See: **Summary of findings for the main comparison** Electrical stimulation versus no active treatment; **Summary of findings 2** Electrical stimulation versus placebo or sham treatment; **Summary of findings 3** Electrical stimulation versus pelvic floor muscle training (PFMT); **Summary of findings 4** Electrical stimulation versus pelvic floor muscle training (PFMT) plus biofeedback; **Summary of findings 5** Electrical stimulation versus magnetic stimulation; **Summary of findings 6** Electrical stimulation versus laseropuncture/electro-acupuncture; **Summary of findings 7** Electrical stimulation versus drug therapy; **Summary of findings 8** Electrical stimulation plus pelvic floor muscle training (PFMT) versus PFMT alone; **Summary of findings 9** Electrical stimulation plus behavioural therapy versus behavioural therapy alone; **Summary of findings 10** Electrical stimulation plus drug therapy versus drug therapy alone; **Summary of findings 11**

Electrical stimulation (ES) once a week versus ES twice a week; **Summary of findings 12** Electrical stimulation (ES) once a week versus ES three times a week; **Summary of findings 13** Sensory threshold electrical stimulation (ES) versus motor threshold ES

1. Electrical stimulation versus no active treatment

Five trials with 336 participants compared ES with no active treatment (Berghmans 2002; Monteiro 2014; Oldham 2013; Svihra 2002; Vahtera 1997).

Primary outcomes

Perception of cure or improvement of OAB symptoms

Two trials reported subjective cure or improvement (Monteiro 2014; Oldham 2013). Low-quality evidence indicated that participants receiving ES were more likely to report cure or improvement in symptoms than those receiving no active treatment (RR 1.85, 95% CI 1.34 to 2.55; n = 121) (Analysis 1.1; Summary of findings for the main comparison).

Number of participants satisfied with treatment

Not reported

Improvement in urgency urinary incontinence (UUI)

Not reported

OAB-related quality of life

Two trials (Oldham 2013, Svihra 2002) reported QoL measured by the following instruments:

- International Consultation on Incontinence Questionnaire (ICI-Q);
- Incontinence Quality of Life Questionnaire (I-QoL);
- Behavioural Urge Score (BUS); and
- International Prostate Symptom Score (IPSS)

Low quality evidence indicated no evidence of a difference in quality of life between those undergoing ES and those who received no active treatment (Summary of findings for the main comparison; Table 2).

Secondary outcomes

Quantification of symptoms

One trial reported a statistically significant effect in favour of ES in terms of nocturia and daytime frequency (Marques 2008) but without giving any raw data (Table 2).

One trial reported symptom outcomes at two different time points (Monteiro 2014), which suggested that the effectiveness of ES did not diminish over time (Table 2).

Economic data

Not reported

Procedure outcomes

Not reported

Adverse effects

Not reported

2. Electrical stimulation versus placebo or sham treatment

Eighteen trials with 1569 participants compared ES to placebo or sham treatment: drug placebo: Kosilov 2013; Wang 2006; Wang 2009; and sham ES: Amaro 2006; Barroso 2002; Bellette 2009; Booth 2013; Bower 1998; Brubaker 1997; Finazzi-Agrò 2010; Kennelly 2011; Peters 2010; Shepherd 1984; Shepherd 1985; Slovak 2015; Vohra 2002; Walsh 2001; Yamanishi 2000a.

Primary outcomes

Perception of cure or improvement of OAB symptoms

Based on four trials (Bellette 2009; Wang 2006; Wang 2009; Yamanishi 2000a), participants receiving ES were almost three times more likely than those in the placebo or sham treatment groups to be cured, according to subjective assessment (RR 2.69, 95% CI 1.39 to 5.21; n = 189) (Analysis 2.1).

Moderate-quality evidence, based on 10 trials, suggested that participants receiving ES were more than twice as likely as those in the placebo or sham treatment groups to report cure or improvement of OAB symptoms (RR 2.26, 95% CI 1.85 to 2.77; n = 677) (Analysis 2.2; Summary of findings 2) (Bellette 2009; Booth 2013; Finazzi-Agrò 2010; Kennelly 2011; Peters 2010; Slovak 2015; Vohra 2002; Wang 2006; Wang 2009; Yamanishi 2000a). Heterogeneity was high ($I^2 = 66%$) but the estimate of effect remained statistically significant with a random-effects model (RR 2.46, 95% CI 1.60 to 3.80).

Moderate-quality evidence relating to subjective cure or improvement showed that percutaneous tibial nerve stimulation was more effective than sham or placebo treatment (RR 3.19, 95% CI 2.22 to 4.58; n = 304) (Booth 2013; Finazzi-Agrò 2010; Peters 2010;

Vohra 2002), while intravaginal ES showed an even greater effect (RR 5.46, 95% CI 2.33 to 12.81; n = 94) (Wang 2006; Wang 2009) (Analysis 2.3).

Number of participants satisfied with treatment

Two small trials (Amaro 2006; Yamanishi 2000a) showed that participants undergoing ES were more likely to report satisfaction with treatment than those receiving sham ES (RR 1.44, 95% CI 1.02 to 2.04; n = 98) (Analysis 2.4).

Improvement in urgency urinary incontinence

Moderate-quality evidence supported the use of ES in terms of improvement in UUI when compared to placebo or sham treatment (RR 2.23, 95% CI 1.46 to 3.40), however, heterogeneity was high ($I^2 = 78\%$), probably due to the large differences in effect sizes between the trials (Finazzi-Agrò 2010; Peters 2010). A random-effects model still favoured ES but the result was no longer statistically significant (RR 5.03, 95% CI 0.28 to 89.88; n = 242) (Analysis 2.5; Summary of findings 2).

OAB-related quality of life

Seven trials reported a measure of QoL related to OAB or incontinence. One trial used an instrument that was not validated (Yamanishi 2000a); the other instruments used were:

- International Consultation on Incontinence Questionnaire - Urinary Incontinence (ICIQ-UI) (Booth 2013; Oldham 2013);
- Overactive Bladder Questionnaire (OAB-Q) (Bellette 2009; Peters 2010); and
- Incontinence Quality of Life (I-QOL) (Finazzi-Agrò 2010; Svihra 2002).

Three trials reported statistically significant differences in favour of ES in QoL scores (Bellette 2009; Peters 2010; Yamanishi 2000a) but the other trials found no evidence of a difference (Table 3); these results were based on very low-quality evidence (Summary of findings 2).

Secondary outcomes

Quantification of symptoms

ES was found to be more effective than placebo or sham treatment for the following outcomes.

- Incontinence episodes (per 24 hours): MD -1.43, 95% CI -1.92 to 0.95; n = 143) (Analysis 2.7) (Barroso 2002; Kosilov 2013).
- Nocturia episodes (per night): MD -0.37, 95% CI -0.73 to -0.02; n = 245 (Analysis 2.8) (Bellette 2009; Peters 2010).

- Micturitions (per 24 hours): MD -1.09, 95% CI -1.70 TO -0.47; n = 285 (Analysis 2.9) (Amaro 2006; Bellette 2009; Peters 2010).

One trial (Kosilov 2013) measured the number of incontinence episodes at two time points. At the end of six months' treatment there was no evidence of a difference between ES and placebo (MD -0.50, 95% CI -1.18 to 0.18) but at 12 months after baseline there were significantly fewer incontinence episodes in the ES group than the placebo group (MD -1.10, 95% CI -1.82 to -0.38; n = 107). The pooled estimate of effect reported above used the 12-month data from Kosilov 2013 but the result did not change substantially if the six-month data were used (pooled MD -1.13, 95% CI -1.59 to -0.66).

One trial (Yamanishi 2000a) found no evidence of a difference between groups in the number of pads used per 24 hours (Table 3).

Economic data

Not reported

Procedure outcomes

Not reported

Adverse effects

Low-quality evidence indicated no evidence of a difference between ES and placebo or sham treatment in the number of adverse effects (RR 1.24, 95% CI 0.84 to 1.83; n = 450) (Analysis 2.10) (Kennelly 2011; Peters 2010; Yamanishi 2000a) (Summary of findings 2). Adverse effects reported by participants included skin irritation, urinary tract infection, vaginal pain, discomfort and tingling.

3. Electrical stimulation versus other conservative treatments

Eleven trials with 882 participants compared ES to other conservative treatments (Arruda 2008; Berghmans 2002; Boaretto 2011; Olmo Carmona 2013; Kosilov 2013; Lima 2011; Schreiner 2010; Schreiner 2014; Spruijt 2003; Wang 2004; Yamanishi 2000b).

i) ES versus pelvic floor muscle training (PFMT)

Seven trials (n = 519) compared ES to PFMT (Arruda 2008; Berghmans 2002; Boaretto 2011; Lima 2011; Schreiner 2014; Spruijt 2003; Wang 2004).

Primary outcomes

Perception of cure or improvement of OAB symptoms

One small trial (n = 22) reported the number of participants cured and found no significant difference between ES and PFMT (Table 4) (Arruda 2008).

Based on three trials, moderate-quality evidence indicated that ES was better than PFMT in terms of cure or improvement of OAB symptoms (RR 1.60, 95% CI 1.19 to 2.14; n = 195) (Analysis 3.1) (Arruda 2008; Schreiner 2014; Wang 2004) (Summary of findings 3).

Number of participants satisfied with treatment

Data from two trials, one of which was a three-arm trial with two different ES groups, suggested that participants were significantly more likely to be satisfied with PFMT treatment with ES (RR 0.76, 95% CI 0.60 to 0.96; n = 102) (Analysis 3.2) (Arruda 2008; Boaretto 2011).

Improvement in urgency urinary incontinence (UUI)

Very low-quality evidence from a single trial (Wang 2004) found no evidence of a difference between ES and PFMT in terms of improvement in UUI (RR 1.62, 95% CI 0.51 to 5.12) (Table 4, Summary of findings 3).

OAB-related quality of life (QoL)

Very low-quality evidence, from a single trial, suggested better QoL in the ES group than the PFMT group (Wang 2004) (Summary of findings 3).

Secondary outcomes

Quantification of symptoms

One small trial (Arruda 2008; n = 22) found no evidence of a difference between ES and PFMT in incontinence episodes, daily micturitions, pads per day or nocturia episodes (Table 4).

Economic data

Not reported

Procedure outcomes

Not reported

Adverse effects

Not reported

ii) ES versus PFMT plus biofeedback

One trial (n = 120) compared ES to biofeedback-assisted PFMT (Wang 2004).

Primary outcomes

Perception of cure or improvement of OAB symptoms

Low-quality evidence from one trial (Wang 2004) found no evidence of a difference between ES and PFMT plus biofeedback in terms of improvement in UUI (RR 1.06, 95% CI 0.60 to 1.85) (Summary of findings 4; Table 5).

Number of participants satisfied with treatment

Not reported

OAB-related quality of life (QoL)

Low-quality evidence from the same trial (Wang 2004) suggested no evidence of a difference in OAB-related QoL measured by the King's Health Questionnaire (MD -5.78 (95% CI -88.99 to 77.43) (Summary of findings 4; Table 5).

Secondary outcomes

None of the secondary outcomes were reported.

iii) ES versus PFMT plus behavioural therapy

One trial compared ES to PFMT plus behavioural therapy (Berghmans 2002) but none of the outcomes of interest were reported.

iv) ES versus magnetic stimulation

Primary outcomes

One trial (Yamanishi 2000b) compared ES to magnetic stimulation but did not report any of our primary outcomes.

Secondary outcomes

Quantification of symptoms

Not reported

Economic data

Not reported

Procedure outcomes

Not reported

Adverse effects

Very low-quality evidence from one trial (n = 32) indicated no evidence of a difference between ES and magnetic stimulation in the numbers of participants with adverse effects (no adverse effects in either group) (Yamanishi 2000b) (Summary of findings 5).

v) ES versus laseropuncture/electro-acupuncture

One trial compared ES to laseropuncture (Kosilov 2013; n = 229) and another compared ES to electro-acupuncture (Olmo Carmona 2013; n = 22).

Primary outcomes

Perception of cure or improvement of OAB symptoms

Not reported

Number of participants satisfied with treatment

Not reported

OAB-related quality of life

Moderate-quality evidence, from one trial, reported significantly better QoL scores (Olmo Carmona 2013;) in the ES group than in the electro-acupuncture group (Summary of findings 6) (Table 6).

Secondary outcomes

Quantification of symptoms

Based on two trials, there were significantly fewer incontinence episodes in the ES groups than in those receiving laseropuncture or electro-acupuncture (MD -1.84, 95% CI -2.33 to -1.35; n = 136) (Analysis 4.1) (Olmo Carmona 2013; Kosilov 2013). Kosilov 2013 (n = 114) reported the number of incontinence episodes at two time points; after six months' treatment there were significantly fewer incontinence episodes in the ES group (MD - 1.60, 95% CI -1.92 to -1.28) and after nine months' follow-up the difference increased to -1.80 (95% CI -2.30 to 1.30). The pooled results reported above included the nine-month follow-up data from this trial; replacing it with the six-month data changed the result to MD -1.62 (95% CI -1.93 to -1.30). Additionally, the other trial (Olmo Carmona 2013; n = 22) reported mean numbers of micturitions and nocturia episodes but found no evidence of a difference in number of micturitions or nocturia episodes (Table 6).

Economic data

Not reported

Procedure outcomes

Not reported

Adverse effects

Not reported

4. Electrical stimulation versus drug therapy

Twenty-three trials with 1756 participants compared ES to the following drug treatments.

- Oestrogen cream (Abdelbary 2015)
- Oxybutynin: immediate release (Arruda 2008; Boaretto 2011); extended-release (Manriquez 2013); not reported if extended or immediate release (Soomro 2001; Souto 2014; Svihra 2002; Wang 2006; Wang 2009; Wise 1993)
- Probantheline bromide (Smith 1996)
- Probanthine (Aaronson 1995)
- Solifenacin succinate (Chen 2015; Vecchioli-Scaldazza 2013)
- Terodiline (Wise 1992)
- Tolterodine, extended-release (Peters 2009)
- Tolterodine (not reported if extended or immediate release (Franzén 2010; Lin 2004; Preyer 2007; Preyer 2015; Sancaktar 2010)

- Trospium and solifenacin (Kosilov 2013)
- Unspecified anticholinergic agent (Orhan 2015)

Primary outcome

Perception of cure or improvement of OAB symptoms

Overall, there was no evidence of a difference between ES and drug treatment in curing OAB (RR 0.98, 95% CI 0.69 to 1.41; n = 388). Nor was there any evidence of a difference between ES and individual drugs (tolterodine (Franzén 2010; Lin 2004; Peters 2009), oxybutynin (Arruda 2008; Wang 2006; Wang 2009), propantheline bromide (Smith 1996)) (Analysis 5.1).

When measuring cure or improvement together, moderate-quality evidence suggested that ES was more effective than drug treatment overall (RR 1.20, 95% CI 1.04 to 1.38; n = 439) but no evidence of a difference was found when comparing ES to individual drugs (tolterodine (Franzén 2010; Lin 2004; Peters 2009), oxybutynin (Arruda 2008; Wang 2006; Wang 2009), propantheline bromide (Smith 1996)) (Analysis 5.2). Another trial (Aaronson 1995) reported data not suitable for meta-analysis but found that 69% of participants receiving ES were cured or improved compared to 50% of participants taking probanthine (Summary of findings 7). With regard to cure or improvement of OAB symptoms, a subgroup analysis based on low-quality evidence found that ES delivered through intravaginal or transanal routes was more effective than drug treatment (RR 1.28, 95% CI 1.03 to 1.59; n = 199) (Analysis 5.3), but there was no evidence of a difference in cure or improvement between transcutaneous posterior tibial nerve stimulation and drug treatment (RR 0.51, 95% CI 0.23 to 1.13; n = 64).

There was no evidence of a difference in the number of people satisfied with ES or drug therapy with oxybutynin (RR 0.90, 95% CI 0.72 to 1.14; n = 125) (Arruda 2008; Boaretto 2011) (Analysis 5.4).

Number of participants satisfied with treatment

Not reported

Improvement in urgency urinary incontinence

None of the trials comparing ES to drug treatment reported improvement in UUI.

OAB-related quality of life

Based on low-quality evidence from two trials comparing ES to solifenacin succinate (Chen 2015; Vecchioli-Scaldazza 2013) and another trial comparing ES to vaginal oestrogen cream (Abdelbary 2015), there was no evidence of a difference between the groups

in terms of I-QoL, OAB-Q and PPIUS scores. However, statistically significant differences in favour of ES over drug therapy were reported, measured by an unspecified QoL instrument and the Patient Globe Impression of Improvement tool (Summary of findings 7; Table 7).

The Orhan 2015 trial reported that they found a statistically significantly higher improvement in the ES group than in the anticholinergic group according to three QoL measures; Urinary Distress Inventory (UDI-6), Incontinence Impact Questionnaire (IIQ-7), Over Active Bladder symptom scores (OABSS). However, no raw data were reported.

One trial reported QoL measured at three different time points; at the end of treatment and at three and six months' follow-up (Abdelbary 2015). The data suggested better QoL of life in the ES group initially but at six months there was no evidence of a difference between ES and vaginal oestrogen cream.

Secondary outcomes

Quantification of symptoms

Overall, ES was more effective than drug treatment in terms of incontinence episodes per 24 hours (MD 0.24, 95% CI 0.09 to 0.38; n = 477); however, heterogeneity was high ($I^2 = 96%$) and the result was no longer statistically significant in a random-effects model (MD 0.25, 95% CI -1.11 to 1.60) (Analysis 5.5) (Abdelbary 2015; Arruda 2008; Kosilov 2013; Peters 2009; Vecchioli-Scaldazza 2013).

Comparing ES to individual drugs, one trial reported significantly more incontinence episodes in the ES group than the trospium plus solifenacin group (MD 2.20, 95% CI 1.78 to 2.62; n = 110) (Kosilov 2013) but there was no evidence of a difference between ES and tolterodine (Peters 2009), oxybutynin (Arruda 2008) or oestrogen cream (Abdelbary 2015) in incontinence episodes.

There was insufficient evidence of a difference between ES and drug treatment for the following outcomes (Analysis 5.6; Analysis 5.7; Analysis 5.8 and Table 7).

- Urgency episodes
- Number of micturitions per 24 hours
- Nocturia episodes
- Number of people with nocturia
- Pads used per day

Economic data

One cost-effectiveness study (Chen 2012) found that percutaneous tibial nerve stimulation (PTNS) was not cost-effective compared to extended release tolterodine (incremental cost-effectiveness ratio (ICER) of USD 70,754 per quality-adjusted life year, USD 20,754 above the USD 50,000 acceptable threshold). The probability of cost-effectiveness at the USD 50,000 threshold was 21%.

Procedure outcomes

Not reported

Adverse effects

The reported adverse effects included dry mouth, constipation, headache, skin irritation, blurred vision, muscular pain, indigestion, nausea and dizziness. Due to the variety of adverse effects associated with different drugs, we did not pool the data to obtain one overall estimate effect, as this may have led to a misleading result.

Comparing ES to individual drugs, low-quality evidence suggested fewer adverse effects with ES than with oxybutynin (RR 0.11, 95% CI 0.01 to 0.84; n = 79) (Svihra 2002; Wise 1993). Moderate-quality evidence indicated fewer adverse effects with ES than with tolterodine (RR 0.12, 95% CI 0.05 to 0.27; n = 200) (Franzén 2010; Lin 2004; Preyer 2007; Preyer 2015) but there was no evidence of a difference in adverse effects between ES and solifenacin succinate (Chen 2015) (very low-quality evidence) (Analysis 5.9) (Table 7).

5. Electrical stimulation versus surgery

No studies were identified that compared ES with surgery. However, one economic evaluation was identified (Robinson 2010), which found that PTNS was more cost-effective than botulinum toxin (ICER GBP 50,133 and GBP 111,953 respectively), although neither treatment would be considered cost-effective according to the thresholds used by the UK's National Institute for Health and Care Excellence.

6. Electrical stimulation plus another treatment versus another treatment alone

i) ES plus PFMT versus PFMT alone

Five trials (203 participants) compared ES plus PFMT to PFMT alone (Firra 2013; Gaspard 2014; Lo 2003; Schmidt 2009; Schreiner 2010).

Primary outcome

Perception of cure or improvement of OAB symptoms

None of the trials comparing ES plus another treatment versus another treatment alone reported cure or improvement.

Based on two small trials (Gaspard 2014; Schreiner 2010), significantly more participants reported satisfaction with ES plus PFMT than PFMT alone (RR 1.58, 95% CI 1.13 to 2.20; n = 82) (Analysis 6.1).

Number of participants satisfied with treatment

Not reported

Improvement in urgency urinary incontinence

Low-quality evidence from one small trial (Schreiner 2010) found that participants receiving ES plus PFMT were more than twice as likely to report improvement in UUI (RR 2.82, 95% CI 1.44 to 5.52; n = 51) (Table 8; Summary of findings 8)

OAB-related quality of life

Low-quality evidence from three trials suggested no evidence of a difference between groups in QoL scores when measured with SF-Qualiveen and York Incontinence Perception Scale but there was better QoL in the ES plus PFMT group in one trial reporting ICIQ-SF scores (Summary of findings 8; Table 8).

Secondary outcomes

Quantification of symptoms

Data from two trials suggested that adding ES to PFMT was more effective than PFMT alone in terms of incontinence episodes (MD -0.83, 95% CI -1.47 to -0.19; n = 119) (Firra 2013; Gaspard 2014). However, heterogeneity was high ($I^2 = 61%$), probably due to the differences between trials in direction of effect. A random-effects analysis altered the result so that it was no longer statistically significant (MD -0.60, 95% CI -1.84 to 0.64) (Analysis 6.2). In terms of urgency episodes, two trials found that ES with PFMT was better than PFMT alone (MD -2.49 (-2.74 to -2.24) but there was unexplained heterogeneity ($I^2 = 87%$) and a random-effects analysis maintained a statistically significant result but with wider confidence intervals (MD -2.33, 95% CI -3.11 to -1.54; n = 248) (Analysis 6.3) (Firra 2013; Gaspard 2014). Data from two trials showed no evidence of a difference in micturitions per day between ES plus PFMT and PFMT alone. One trial found that adding ES to PFMT was more effective than PFMT alone in terms of number of nocturia episodes (Schreiner 2010) (Table 8).

Economic data

Not reported

Procedure outcomes

Not reported

Adverse effects

Very low-quality evidence from a single trial found no evidence of a difference between ES plus PFMT and PFMT only in the number of people with adverse effects ([Summary of findings 8; Table 8](#)).

Other outcomes

Further data from a trial comparing ES plus PFMT to PFMT alone ([Firra 2013](#)) are presented in [Table 8](#). These data relate to pelvic floor muscle strength and are inconclusive.

ii) ES plus behavioural therapy versus behavioural therapy alone

One trial ([Gonzalez 2015](#); n = 82) compared ES plus behavioural therapy to behavioural therapy alone.

Primary outcome

Perception of cure or improvement of OAB symptoms

Not reported

Number of participants satisfied with treatment

Not reported

Improvement in urgency urinary incontinence

Not reported

OAB-related quality of life

Very low-quality evidence from a single trial ([Gonzalez 2015](#)) suggested higher QoL when ES was added to behavioural therapy ([Summary of findings 9; Table 9](#)).

Secondary outcomes

Not reported

iii) ES plus drug therapy versus drug therapy alone

Three trials compared ES plus drug therapy to drug therapy alone ([Abdelbary 2015](#); [Orhan 2015](#); [Souto 2014](#))

Primary outcome

Perception of cure or improvement of OAB symptoms

Not reported

Number of participants satisfied with treatment

Not reported

Improvement in urgency urinary incontinence

Not reported

OAB-related quality of life

Low-quality evidence, from two trials, suggested there may be no difference in QoL when ES was added to drug therapy (tolterodine or vaginal oestrogen cream) (SMD -1.50 (95% CI -3.72 to 0.72; n = 248) ([Analysis 7.1](#)) ([Summary of findings 10](#)) ([Abdelbary 2015](#); [Sancaktar 2010](#)).

The trial by [Abdelbary 2015](#) measured QoL at three different time points; at the end of treatment and at three and six months' follow-up. There was a statistically significant difference in favour of ES plus oestrogen cream at all time points ([Table 10](#)).

Secondary outcomes

Quantification of symptoms

Data from two trials suggested that adding ES to drug therapy (tolterodine or oestrogen cream) resulted in significantly fewer incontinence episodes than drug therapy alone (MD -0.53, 95% CI -0.63 to -0.43; n = 248) ([Abdelbary 2015](#); [Sancaktar 2010](#)) ([Analysis 7.2](#)). However, heterogeneity was very high ($I^2 = 97%$), probably due to considerable differences in sample sizes. A random-effects analysis altered the result slightly but it remained statistically significant (MD -0.60, 95% CI -1.18 to -0.02).

ES added to drug therapy (tolterodine or oestrogen cream) also resulted in significantly fewer urgency episodes (MD -2.49, 95% CI -2.74 to -2.24; 248) ([Abdelbary 2015](#); [Sancaktar 2010](#)) ([Analysis 7.3](#)). Again, heterogeneity was high ($I^2 = 87%$) and a random-effects analysis altered the result only slightly (MD -2.33, 95% CI -3.11 to -1.54).

However, no evidence of a difference was found in the following outcomes when comparing ES plus drug therapy to drug therapy

alone micturitions per 24 hours (Abdelbary 2015; Souto 2014; n = 250) (tolterodine or oxybutynin) (Analysis 7.4)

The trial by Abdelbary 2015 (n = 210) measured symptoms at three different time points; at the end of treatment and at three and six months' follow-up. In almost all cases, the result suggested adding ES to oestrogen cream was more effective than oestrogen cream alone.

Economic data

Not reported

Procedure outcomes

Not reported

Adverse effects

Very low-quality evidence from a single trial indicated no evidence of a difference in adverse effects when ES was added to tolterodine compared to tolterodine alone (Sancaktar 2010; n = 38) (Summary of findings 10; Table 10). The reported adverse effects included constipation, dry mouth, headache and skin irritation.

7. One type of electrical stimulation versus another type of electrical stimulation

Ten trials with 533 participants compared one type of ES with another (Alves 2015; Boaretto 2011; Bower 1998; Finazzi-Agrò 2005; Lobel 1998; Monga 2011; Phillips 2012; Seth 2014; Slovak 2015; Sotelo 2011).

Primary outcome

Perception of cure or improvement of OAB symptoms

Very low-quality evidence from a single trial (Lobel 1998; n = 37), comparing ES once a week versus ES twice a week, found that all participants were improved after five weeks of treatment and that 24% (9/37) were satisfied enough to request no further treatment. However, these data were not reported separately for the two treatment groups (Summary of findings 11; Table 11). Finazzi-Agrò 2005 (n = 35), which compared one session of percutaneous ES per week to three sessions per week, found little evidence of a difference between the groups in terms of successful treatment. Success was defined as greater than 50% reduction in micturitions per 24 hours, or as greater than 50% reduction in UUI episodes in participants who had UUI at baseline (Summary of findings 12; Table 11). Again, the quality of evidence was very low.

Number of participants satisfied with treatment

Not reported

OAB-related quality of life

Very low-quality evidence, from a single trial (Alves 2015; n = 28) comparing sensory threshold ES to motor threshold ES, suggested there was no evidence of a difference in QoL measured with ICIQ-OAB (Summary of findings 13; Table 11). Similarly, very low-quality evidence from another trial (Finazzi-Agrò 2005) suggested little evidence of a difference in I-QoL scores when once a week ES was compared to three times per week (Summary of findings 12).

Secondary outcomes

Quantification of symptoms

One trial (Monga 2011; n = 74), comparing ES patches placed by investigators versus patches placed by participants, reported various outcomes relating to quantification of symptoms but did not separate the data according to treatment group.

Another small trial (Alves 2015; n = 28), comparing two different kinds of tibial nerve stimulation found no evidence of a difference between treatments in the number of UUI episodes, urgency episodes, micturitions or nocturia episodes (Table 11). Similarly, the Finazzi-Agrò 2005 trial (n = 35) comparing ES delivered once a week to ES three times per week, reported little evidence of a difference between the groups in incontinence episodes and micturitions per 24 hours (Table 11).

No other outcomes relating to quantification of symptoms were reported by any of the identified trials.

Economic data

Not reported

Procedure outcomes

Not reported

Adverse effects

One trial (n = 37; Lobel 1998), comparing ES once a week versus ES twice a week, reported the following adverse effects across all participants but not separated by treatment group.

- Discomfort: 16% (6/37)
- Leg tremor: 8% (3/37)
- Urinary tract infection: 8% (3/37)

Another trial (n = 50; Sotelo 2011), comparing different ES patch placements, reported one participant experiencing adverse effects

but did not report to which treatment group the participant belonged. Very low-quality evidence from [Finazzi-Agrò 2005](#), comparing one ES session per week to three sessions per week, reported no adverse effects in either group ([Summary of findings 12](#)).

Other outcomes

One trial ([Boaretto 2011](#)) compared two different pulse widths (200 microseconds and 500 microseconds) and reported similar satisfaction in both groups (RR for number of people not satisfied: 0.73, 95% CI 0.25 to 2.10; n = 38) ([Table 11](#)).

ADDITIONAL SUMMARY OF FINDINGS *[Explanation]*

Electrical stimulation versus placebo or sham treatment						
Patient or population: Adults with overactive bladder (OAB) Setting: Hospitals (Brazil, Italy, Japan, Taiwan, USA, UK) Intervention: Electrical stimulation Comparison: Placebo or sham treatment						
Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	No. of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with placebo or sham treatment	Risk with electrical stimulation				
Participants cured or improved Follow-up: range 4 weeks to 12 weeks	Study population 262 per 1000	593 per 1000 (485 to 726)	RR 2.26 (1.85 to 2.77)	677 (10 RCTs)	⊕⊕⊕○ MODERATE ¹	
Participants with improvement in urgency urinary incontinence Follow-up: range 4 weeks to 13 weeks	Study population 189 per 1000	948 per 1000 (53 to 1000)	RR 5.03 (0.28 to 89.88)	242 (2 RCTs)	⊕⊕○○ LOW ²³	
OAB-related quality of life Follow-up: range 4 weeks to 13 weeks	3/7 trials reported significantly higher quality of life in the intervention groups. Others reported no evidence of a difference between groups		-	627 (7 RCTs)	⊕⊕○○ LOW ²⁴	
Adverse effects Follow-up: median 12 weeks	Study population 139 per 1000	172 per 1000 (117 to 254)	RR 1.24 (0.84 to 1.83)	450 (3 RCTs)	⊕⊕○○ LOW ²⁵	

* **The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; RR: Risk ratio; OR: Odds ratio

GRADE Working Group grades of evidence

High quality: We are very confident that the true effect lies close to that of the estimate of the effect

Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect

Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

¹ Downgraded one level due to serious risk of bias (high risk of performance and detection bias in one trial; unclear risk of bias in many domains in other trials)

² Downgraded one level due to serious imprecision (small sample sizes and events, wide confidence interval of the pooled effect estimate)

³ Downgraded one level due to serious risk of bias (unclear sequence generation and allocation concealment in the included studies).

⁴ Downgraded one level due to serious risk of bias (unclear risk of bias in most domains)

⁵ Downgraded one level due to serious risk of bias (unclear risk of selection bias)

Electrical stimulation versus PFMT						
Patient or population: Adults with overactive bladder (OAB) Setting: Hospitals (Brazil, Taiwan) Intervention: Electrical stimulation Comparison: PFMT						
Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	No. of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with PFMT	Risk with electrical stimulation				
Participants cured or improved Follow-up: median 12 months	Study population 390 per 1000	625 per 1000 (465 to 836)	RR 1.60 (1.19 to 2.14)	195 (3 RCTs)	⊕⊕⊕○ MODERATE ¹	
Participants with improvement in urgency urinary incontinence Follow-up: 6 weeks	Study population 382 per 1000	619 per 1000 (195 to 1000)	RR 1.62 (0.51 to 5.12)	52 (1 RCT)	⊕○○○ VERY LOW ^{2,3}	
OAB-related quality of life assessed with: King's Health Questionnaire (lower scores indicate better quality of life) Follow-up: 6 weeks	The mean OAB-related quality of life in the intervention group was 129.81 higher (47.83 higher to 211.79 higher)		-	49 (1 RCT)	⊕○○○ VERY LOW ^{2,3}	
Adverse effects	See comment	See comment	Not estimable	(0 studies)	-	Not reported

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio; **OR:** Odds ratio

GRADE Working Group grades of evidence

High quality: We are very confident that the true effect lies close to that of the estimate of the effect

Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect

Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

¹ Downgraded one level due to serious risk of bias (some risk of performance and attrition bias)

² Downgraded two levels due to very serious risk of bias (unclear risk of selection and detection bias)

³ Downgraded two levels due to very serious imprecision (single trial, small sample size, wide confidence interval)

Electrical stimulation versus PFMT plus biofeedback						
Patient or population: Adults with overactive bladder (OAB) Setting: Hospital (Taiwan) Intervention: Electrical stimulation Comparison: PFMT plus biofeedback						
Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	No. of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with PFMT plus biofeedback	Risk with electrical stimulation				
Participants cured or improved	See comment	See comment	Not estimable	(0 studies)	-	Not reported
Participants with improvement in urgency urinary incontinence Follow-up: 6 weeks	Study population		RR 1.06 (0.60 to 1.85)	51 (1 RCT)	⊕⊕○○ LOW ¹²	
	500 per 1000	530 per 1000 (300 to 925)				
OAB-related quality of life Assessed with: King's Health Questionnaire (lower scores indicate better quality of life) Follow-up: 6 weeks	The mean OAB-related quality of life in the intervention group was 5.78 lower (88.99 lower to 77.43 higher)		-	51 (1 RCT)	⊕⊕○○ LOW ¹²	No evidence of a difference between groups in quality of life scores
Adverse effects	See comment	See comment	Not estimable	(0 studies)	-	Not reported

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

CI: Confidence interval; RR: Risk ratio; OR: Odds ratio

GRADE Working Group grades of evidence

High quality: We are very confident that the true effect lies close to that of the estimate of the effect

Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect

Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

¹ Downgraded one level due to serious risk of bias (unclear risk of selection and performance bias)

² Downgraded one level due to serious imprecision (single trial, small sample size)

Electrical stimulation versus magnetic stimulation						
Patient or population: Adults with overactive bladder (OAB) Setting: Hospital (Japan) Intervention: Electrical stimulation Comparison: Magnetic stimulation						
Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	No. of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with magnetic stimulation	Risk with electrical stimulation				
Participants cured or improved	See comment	See comment	Not estimable	(0 studies)	-	Not reported
Participants with improvement in urgency urinary incontinence	See comment	See comment	Not estimable	(0 studies)	-	Not reported
OAB-related quality of life	See comment	See comment	Not estimable	(0 studies)	-	Not reported
Adverse effects Follow-up: 4 weeks	0 per 1,00	0 per 1,00 (0 to 0)	Not estimable	32 (1 RCT)	⊕○○○ VERY LOW ¹²	No events reported in either group

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

CI: Confidence interval; RR: Risk ratio; OR: Odds ratio

GRADE Working Group grades of evidence

High quality: We are very confident that the true effect lies close to that of the estimate of the effect

Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect

Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

¹ Downgraded two levels due to very serious imprecision (single trial, small sample size)

² Downgraded one level due to serious risk of bias (unclear risk of selection and performance bias)

Electrical stimulation versus laseropuncture/electro-acupuncture						
Patient or population: Adults with overactive bladder (OAB) Setting: Hospital (Spain) Intervention: Electrical stimulation Comparison: Laseropuncture/electro-acupuncture						
Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	No. of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with laseropuncture/electro-acupuncture	Risk with electrical stimulation				
Participants cured or improved	See comment	See comment	Not estimable	(0 studies)	-	Not reported
Participants with improvement in urgency urinary incontinence	See comment	See comment	Not estimable	(0 studies)	-	Not reported
OAB-related quality of life Assessed with: Bladder Self-Assessment Questionnaire (lower scores indicate better quality of life) Follow-up: 12 weeks	The mean OAB-related quality of life in the intervention group was 2.09 lower (4.1 lower to 0.08 lower)		-	22 (1 RCT)	⊕⊕○○ LOW ¹	Significantly greater quality of life in intervention group
Adverse effects	See comment	See comment	Not estimable	(0 studies)	-	Not reported

* **The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio; **OR:** Odds ratio

GRADE Working Group grades of evidence

High quality: We are very confident that the true effect lies close to that of the estimate of the effect

Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect

Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

¹ Downgraded two levels due to very serious imprecision (single trial, small sample size)

Electrical stimulation versus drug therapy						
Patient or population: Adults with overactive bladder (OAB) Setting: Hospitals (Brazil, China, Sweden, Taiwan) Intervention: Electrical stimulation (ES) Comparison: Drug therapy						
Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	No. of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with drugs	Risk with electrical stimulation				
Participants cured or improved Follow-up: range 4 weeks to 2 years	Study population		RR 1.20 (1.04 to 1.38)	439 (8 RCTs)	⊕⊕⊕○ MODERATE ¹	
	585 per 1000	702 per 1000 (608 to 807)				
OAB-related quality of life Follow-up: range 4 weeks to 6 months	One trial used OAB-Q, PGII and PPIUS and found a significant result only in the PGII, which was in favour of ES. Another trial found no evidence of a difference between groups in I-QoL scores. A third trial found higher QoL scores in the ES group at the end of treatment and at 3 months' follow-up but no evidence of a difference at 6 months' follow-up		-	336 (3 RCTs)	⊕⊕○○ LOW ¹²	
Adverse effects - ES versus oxybutynin Follow-up: 5 weeks	Study population		RR 0.11 (0.01 to 0.84)	79 (2 RCTs)	⊕⊕○○ LOW ²³	
	214 per 1000	24 per 1000 (2 to 180)				
Adverse effects - ES versus tolterodine Follow-up: range 4 weeks to 2 years	Study population		RR 0.12 (0.05 to 0.27)	200 (4 RCTs)	⊕⊕⊕○ MODERATE ¹	

	459 per 1000	55 per 1000 (23 to 124)			
Adverse effects - ES versus solifenacin succinate Follow-up: 4 weeks	Study population 100 per 1000	9 per 1000 (1 to 160)	RR 0.09 (0.01 to 1.60)	100 (1 RCT)	⊕○○○ VERY LOW ¹⁴

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; RR: Risk ratio; OR: Odds ratio

GRADE Working Group grades of evidence

High quality: We are very confident that the true effect lies close to that of the estimate of the effect

Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect

Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

- ¹ Downgraded one level due to serious risk of bias (unclear risk of bias in most domains)
- ² Downgraded one level due to serious imprecision (few trials, small sample sizes)
- ³ Downgraded one level due to serious risk of bias (high risk of selection and attrition bias)
- ⁴ Downgraded two levels due to very serious imprecision (single trial, wide confidence intervals)

Electrical stimulation plus PFMT versus PFMT alone						
Patient or population: Adults with overactive bladder (OAB) Setting: Hospital (Belgium, Brazil, USA) Intervention: Electrical stimulation plus PFMT Comparison: PFMT alone						
Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	No. of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with PFMT alone	Risk with electrical stimulation plus PFMT				
Participants cured or improved	See comment	See comment	Not estimable	(0 studies)	-	Not reported
Participants with improvement in urgency urinary incontinence Follow-up: 12 weeks	Study population		RR 2.82 (1.44 to 5.52)	51 (1 RCT)	⊕⊕○○ LOW ¹²	
	269 per 1000	759 per 1000 (388 to 1000)				
Adverse effects Follow-up: 12 weeks	Study population		Not estimable	51 (1 RCT)	⊕○○○ VERY LOW ³⁴	No events reported in treatment groups
	0 per 1000	0 per 1000 (0 to 0)				
OAB-related quality of life Follow-up: range 8 weeks to 6 months	One trial found greater quality of life in the intervention group (measured with ICIQ-SF). Two other trials found no evidence of a difference between groups (measured with SF-Qualiveen and York Incontinence Perception Scale)		-	201 (3 RCTs)	⊕⊕○○ LOW ¹²	
Cost-effectiveness	See comment	See comment	Not estimable	(0 studies)	-	Not reported

* **The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio; **OR:** Odds ratio

GRADE Working Group grades of evidence

High quality: We are very confident that the true effect lies close to that of the estimate of the effect

Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

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¹ Downgraded one level due to serious risk of bias (unclear risk of bias in most domains)

² Downgraded one level due to serious imprecision (single trial, small sample, wide confidence interval)

³ Downgraded one level due to serious risk of bias (high risk of attrition bias, unclear risk in other domains)

⁴ Downgraded two levels due to very serious imprecision (single trial, small sample size, no events)

Electrical stimulation plus behavioural therapy versus behavioural therapy alone

Patient or population: Adults with overactive bladder (OAB)
Setting: Hospital (Chile)
Intervention: Electrical stimulation plus behavioural therapy
Comparison: Behavioural therapy

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with behavioural therapy alone	Risk with electrical stimulation plus behavioural therapy				
Participants cured or improved	See comment	See comment	Not estimable	(0 studies)	-	Not reported
Participants with improvement in urgency urinary incontinence	See comment	See comment	Not estimable	(0 studies)	-	Not reported
OAB-related quality of life Follow-up: 3 months	Intervention group reported significantly better quality of life measured with OAB-Q and Incontinence Severity Index		-	82 (1 RCT)	⊕○○○ VERY LOW ¹²	
Adverse effects	See comment	See comment	Not estimable	(0 studies)	-	Not reported

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

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- ¹ Downgraded one level due to serious risk of bias (high risk of attrition bias, low risk of selection bias and unclear in other domains)
- ² Downgraded two levels due to very serious imprecision (single trial, small sample size, wide confidence interval)

Electrical stimulation plus drug therapy versus drug therapy alone						
Patient or population: Adults with overactive bladder (OAB) Setting: Hospital (Turkey) Intervention: Electrical stimulation plus drug therapy Comparison: Drug therapy						
Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	No. of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with drug therapy alone	Risk with electrical stimulation plus drug therapy				
Participants cured or improved	See comment	See comment	Not estimable	(0 studies)	-	Not reported
Participants with improvement in urgency urinary incontinence	See comment	See comment	Not estimable	(0 studies)	-	Not reported
OAB-related quality of life assessed with: IIQ-7 (lower scores indicate greater quality of life) Follow-up: range 12 weeks to 6 months	The mean OAB-related quality of life in the intervention group was 1.50 lower (3.72 lower to 0.72 higher)		-	248 (2 RCTs)	⊕⊕○○ LOW ¹²	
Adverse effects Follow-up: 12 weeks	Study population		RR 0.45 (0.04 to 4.55)	38 (1 RCT)	⊕○○○ VERY LOW ¹³	
	111 per 1000	50 per 1000 (4 to 506)				

* **The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; RR: Risk ratio; OR: Odds ratio

GRADE Working Group grades of evidence

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¹ Downgraded one level due to serious risk of bias (unclear risk of bias in most domains)

² Downgraded one level due to serious imprecision (few trials, confidence intervals do not overlap)

³ Downgraded one level due to very serious imprecision (single trial, small sample size, wide confidence interval)

ES once a week versus ES twice a week			
Patient or population: Adults with overactive bladder (OAB) Setting: Hospital (USA) Intervention: ES once a week Comparison: ES twice a week			
Outcomes	Impact	No. of participants (studies)	Quality of the evidence (GRADE)
Participants cured or improved Follow-up: 6 months	100% (37/37) of participants in both groups reported improvement in symptoms but only 9/37 were satisfied enough to request no further treatment	37 (1 RCT)	⊕○○○ VERY LOW ¹²
Participants with improvement in urgency urinary incontinence	Not reported	(0 studies)	-
<p>*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).</p> <p>CI: Confidence interval; RR: Risk ratio; OR: Odds ratio</p>			
<p>GRADE Working Group grades of evidence</p> <p>High quality: We are very confident that the true effect lies close to that of the estimate of the effect</p> <p>Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different</p> <p>Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect</p> <p>Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect</p>			

¹ Downgraded one level due to serious risk of bias (unclear risk of bias in most domains)

² Downgraded two levels due to very serious imprecision (N=37 participants in trial but numbers not reported per group)

ES once a week versus ES three times a week						
Patient or population: Adults with overactive bladder (OAB) Setting: Hospital (Italy) Intervention: ES once a week Comparison: ES 3 times a week						
Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	No. of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with ES 3 times a week	Risk with ES once a week				
Participants cured or improved (follow-up not reported)	Study population		RR 0.97 (0.60 to 1.57)	35 (1 RCT)	⊕○○○ VERY LOW ¹²	
	667 per 1000	647 per 1000 (400 to 1000)				
Participants with improvement in urgency urinary incontinence (follow-up not reported)	Study population		RR 0.80 (0.29 to 2.21)	22 (1 RCT)	⊕○○○ VERY LOW ¹²	
	455 per 1000	364 per 1000 (132 to 1000)				
OAB-related quality of life (follow-up not reported) assessed with: I-QoL (Higher scores indicate greater quality of life)	I-QoL scores very similar in the 2 groups (median (range) N): once a week: 77 (35-100), 17. 3 times per week: 78 (33-100), 18		-	35 (1 RCT)	⊕○○○ VERY LOW ¹²	
Adverse effects (follow-up not reported)	0 per 1000	0 per 1000 (0 to 0)	not estimable	35 (1 studies)	⊕○○○ VERY LOW ¹²	

* **The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; RR: Risk ratio; OR: Odds ratio

GRADE Working Group grades of evidence

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Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

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¹ Downgraded one level due to serious risk of bias (unclear risk of bias in most domains)

² Downgraded two levels due to very serious imprecision (single trial, small sample size, wide confidence intervals around estimate of effect)

Sensory threshold ES versus motor threshold ES						
Patient or population: Adults with overactive bladder (OAB) Setting: Hospital (Brazil) Intervention: Sensory threshold ES Comparison: Motor threshold ES						
Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	No. of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with motor threshold ES	Risk with sensory threshold ES				
Participants cured or improved	See comment	See comment	Not estimable	(0 studies)	-	Not reported
Participants with improvement in urgency urinary incontinence	See comment	See comment	Not estimable	(0 studies)	-	Not reported
OAB-related quality of life assessed with: ICIQ-OAB Follow-up: 4 weeks	The mean OAB-related quality of life in the intervention group was 0.07 lower (2.21 lower to 2.07 higher)		-	28 (1 RCT)	⊕○○○ VERY LOW ¹²	No evidence of a difference between groups
Adverse effects	See comment	See comment	Not estimable	(0 studies)	-	Not reported

* **The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio; **OR:** Odds ratio

GRADE Working Group grades of evidence

High quality: We are very confident that the true effect lies close to that of the estimate of the effect

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¹ Downgraded one level due to serious risk of bias (low risk of performance, detection and attrition bias but unclear risk of selection bias)

² Downgraded two levels due to very serious imprecision (single trial, small sample, wide confidence interval)

DISCUSSION

Summary of main results

To the best of our knowledge, this is the first systematic review to synthesise all available data from randomised controlled trials (RCTs) relating to the effectiveness of electrical stimulation (ES) with non-implanted devices compared with any other treatment for overactive bladder (OAB). The results of the review suggest that ES shows promise in treating OAB.

Improvement of OAB symptoms

ES is likely to be more effective than placebo/sham treatment, PFMT or drug therapy (Summary of findings 2; Summary of findings 3; Summary of findings 7) in improving OAB symptoms. Specifically considering urgency urinary incontinence (UUI), ES may be more effective than placebo or sham treatment (Summary of findings 2) but we are very uncertain that ES is better for UUI than PFMT, (Summary of findings 3), nor can we be certain that adding ES to PFMT leads to improvement in UUI (Summary of findings 8). The conclusions regarding improvement in UUI should be interpreted with caution due to the lack of clarity in the trials' reporting of rates of urgency incontinence at baseline.

Furthermore, it appears that while both intravaginal ES and percutaneous tibial nerve stimulation are likely to lead to greater improvement in symptoms than sham/placebo, intravaginal ES is likely to have a larger effect.

For OAB symptoms, low-quality evidence indicates that ES may be more effective than no active treatment (Summary of findings for the main comparison). This is supported by evidence from symptom quantification, such as the number of people with nocturia or increased frequency. Additionally, low-quality evidence suggests that ES may be more effective than biofeedback-assisted PFMT (Summary of findings 4) but this is based on a single trial and we did not identify any secondary outcome data to support or refute this finding.

OAB-related quality of life

It is difficult to state with certainty that ES is likely to improve OAB-related quality of life more than treatment with PFMT or electro-acupuncture; notwithstanding the moderate quality of the evidence identified, these findings are based on single small trials and are therefore not conclusive (Summary of findings 3; Summary of findings 6).

Low-quality evidence suggests that ES may lead to improved OAB-related quality of life compared to no active treatment (Summary of findings for the main comparison). We cannot be certain there is any difference in OAB-related QoL between ES and drug therapy (Summary of findings 7), nor when ES is added to PFMT or drug therapy, compared to PFMT or drug therapy alone (Summary of findings 8; Summary of findings 10).

It is possible that ES improves OAB-related QoL more than placebo/sham treatment, and that adding ES to behavioural therapy is better than behavioural therapy alone in terms of OAB-related QoL, but the very low quality of the evidence means that we cannot draw these conclusions with any certainty (Summary of findings 2; Summary of findings 9).

Adverse effects

Low-quality evidence suggests that there may be a lower risk of adverse effects with ES than with oxybutynin or tolterodine (Summary of findings 7).

Due to the very low-quality evidence available, we cannot be certain whether there are fewer adverse effects with ES compared to placebo/sham treatment, magnetic stimulation, electro/laseropuncture or solifenacin succinate (Summary of findings 2; Summary of findings 5; Summary of findings 6; Summary of findings 7). We are also very uncertain whether adding ES to PFMT or to drug therapy results in fewer adverse effects than PFMT or drug therapy alone (Summary of findings 8; Summary of findings 10). Nor can we tell if there is any difference in the risk of adverse effects between different types of ES (Summary of findings 11; Summary of findings 12; Summary of findings 13).

Effectiveness of ES over time

Based on the small number of trials reporting outcomes at the end of treatment as well as after a longer follow-up period, it appears that the effect of ES diminishes after the end of treatment. However, this was also the case for most other interventions and is likely to be due to the nature of the condition. Where ES was found to be more effective than a comparator intervention at the first measurement point, this trend was generally found to be maintained at the longer-term follow-up. Nonetheless, this evidence should be considered in the context that the outcomes measured at multiple time points in this small set of trials tended to be objective measures rather than the more reliable and meaningful subjective report of symptoms.

Overall completeness and applicability of evidence

The included studies do not address all of the objectives of the review because many of them did not report data in a usable way or did not measure the primary outcomes, that is, a subjective report of symptoms. Five trials reported urodynamic outcomes only (Berghmans 2002; Bower 1998; Vahtera 1997; Walsh 2001; Yamanishi 2000b), which was of limited use because subjective, patient-reported cure or improvement should take precedence over objective, clinician-observed outcomes; for instance, a patient may still have OAB according to objective measurements but if their subjective assessment is that of no bothersome symptoms, then usually no further treatment will be required. Future

trials should ensure appropriate subjective outcomes are measured and reported.

Of particular note is the absence of data on subjective cure or improvement from the trials comparing ES plus drug therapy to drug therapy alone. Furthermore, the paucity of data in many of the included trials meant that we could not draw any conclusions regarding adverse effects between ES and placebo/sham treatment or other conservative treatments. Nor can we tell if adding ES to another treatment increases the risk of adverse effects.

Another key outcome, QoL associated with OAB or incontinence, was inadequately addressed by the included studies. While 22 of the 64 trials incorporated a validated measure of QoL, it was difficult to discern a clear picture regarding clinically meaningful results. Two trials included definitions of clinical significance relating to the QoL instruments used (Oldham 2013; Svihra 2002); the QoL findings of those trials were not clinically meaningful. The remaining trials that measured QoL were unclear about the clinical significance of their QoL instruments (Abdelbary 2015; Alves 2015; Bellette 2009; Chen 2015; Finazzi-Agrò 2010; Firra 2013; Gaspard 2014; Gonzalez 2015; Orhan 2015; Peters 2010; Phillips 2012; Sancaktar 2010; Schmidt 2009; Schreiner 2010; Schreiner 2014; Seth 2014; Souto 2014; Vecchioli-Scaldazza 2013; Wang 2004; Wang 2009). It is therefore difficult to form any conclusions regarding the potential for ES to improve QoL in relation to OAB. Nevertheless, the findings presented here are based on evidence from trial populations that were reasonably representative of OAB in clinical practice, including people with both OAB-wet and OAB-dry.

Economic commentary

To supplement the main systematic review of effects, we sought to identify economic evaluations which have compared electrical stimulation with non-implanted electrodes to other treatments. Only one economic evaluation (Chen 2012) was identified. This study was a cost-utility analysis, conducted using the framework of a decision model, comparing percutaneous tibial nerve stimulation (PTNS) with extended release tolterodine. The model was based on direct medical costs, in 2010 USD, during a one year time horizon and the analysis was conducted from a societal perspective. The authors concluded that PTNS was not cost-effective compared to tolterodine (incremental cost-effectiveness ratio (ICER) of USD 70,754 per quality-adjusted life year, USD 20,754 above the USD 50,000 acceptable threshold). Furthermore, sensitivity analyses indicated that the ICER was above the acceptable threshold in nine of eleven possible scenarios. The authors noted that their findings were limited by the quality of the literature.

However, there was a degree of ambiguity in the study. Firstly, it was unclear whether a Markov model or a simple decision tree model was used. Secondly, a societal perspective would generally be expected to incorporate more than direct medical costs so it may be more accurate to consider this analysis to be have been

conducted from a healthcare payer perspective. Finally, it appears that the authors have inaccurately interpreted the eleven scenarios presented in the sensitivity analyses and therefore their conclusions may be misleading.

We did not subject this economic evaluation to critical appraisal and we do not attempt to draw any firm or general conclusions regarding the relative costs or efficiency. The apparent scarcity of relevant economic evaluations indicates that economic evidence regarding is currently lacking.

Quality of the evidence

Despite the large number of identified trials (64), the amount and quality of evidence is insufficient to reach a robust conclusion regarding the effectiveness of ES compared to other active treatments. The sample sizes for individual outcomes were small, which led to downgrading the quality of evidence in some instances because underpowered trials are likely to have a greater degree of imprecision. Small sample sizes in individual trials can also lead to under-powered meta-analyses, which then give inconclusive overall estimates of effect.

Assessing the risk of bias and methodological quality of the included trials was limited by the extent to which adequate details were provided in reports of trials. Future trials should adhere to CONSORT guidelines to ensure clarity and completeness in the reporting of methods (Schulz 2010). Risk of selection bias through randomisation and allocation concealment was generally unclear because of insufficient reporting. The risk of performance bias was also relatively unclear because of a lack of information to judge whether or not participants, healthcare providers and outcome assessors were adequately blinded. In many trials, it would not have been possible to blind participants; however, an element of risk of bias remains where participants were not blinded, because self-reported, subjective outcomes could have been affected by participants' perception of the intervention received, leading to uncertainty regarding the extent to which the estimate of effect was truly attributable to the intervention.

Potential biases in the review process

Every attempt was made to reduce the risk of bias in the review process, with broad inclusion criteria and a comprehensive search strategy to identify eligible trials. There were no language restrictions and we obtained translations of non-English trials wherever possible. The risk of bias was further minimised by two review authors undertaking independent screening of search results and independent data extraction.

However, unclear reporting of trial methods and data, and subsequent problems obtaining clarifications from trial authors limited the extent to which we could meaningfully compare all of the relevant data from the identified trials.

Agreements and disagreements with other studies or reviews

To the best of our knowledge, this is the first systematic review of RCTs to investigate the effectiveness of ES with non-implanted devices compared to any other treatment for OAB. A systematic review focusing on ES of the pelvic floor found evidence in favour of ES for urinary incontinence, with or without OAB symptoms (Jerez-Roig 2013). Similarly, a systematic review investigating ES for any kind of urinary incontinence in women (Schreiner 2013) found evidence suggesting that ES was more effective than other treatments for UUI, but that the evidence for stress urinary incontinence (SUI) or mixed urinary incontinence (MUI) was much less clear. As UUI is one of the key symptoms of OAB, our findings with regard to OAB can be taken together with the reviews by Schreiner and colleagues and Jerez-Roig and colleagues to indicate that ES is effective in treating OAB symptoms. Additionally, our findings are in accord with Berghmans 2013, whose systematic review of ES for any kind of urinary incontinence in men found limited evidence that ES was more effective than sham treatment and that ES enhanced the effectiveness of pelvic floor muscle training (PFMT) in the short term.

Schreiner and colleagues' findings regarding different types of ES were similar to ours in that the heterogeneity of ES interventions in the identified trials was such that no conclusions could be drawn on which types of ES may be more effective than others.

The findings of our review lend further weight to another systematic review (Rai 2012) comparing drug treatment with other active treatments for OAB, which found limited evidence that ES was more effective than drugs in improving OAB symptoms and that there were fewer adverse effects associated with ES than with drug treatment. Our review identified eight additional trials not included by Rai 2012; consequently, the conclusions of our review add strength to the evidence base for ES compared to drug treatment.

AUTHORS' CONCLUSIONS

Implications for practice

In conducting this review we have attempted to answer several clinical questions.

- **Is electrical stimulation (ES) with non-implanted devices better than no active treatment, placebo or sham treatment?** Moderate-quality evidence suggests that ES is more effective than no active treatment, placebo or sham treatment in improving overactive bladder (OAB) symptoms, urgency urinary incontinence (UUI) and OAB-related quality of life (QoL).

- **Is one type of ES with non-implanted devices better than another?** No clear evidence was identified to suggest that one type of ES was more effective than others. There was substantial heterogeneity in the types of ES interventions in the included studies. The variety of aspects of treatment such as duration and frequency, duty cycle, current, route of administration (e.g. vaginal, rectal) and approaches of electrodes (e.g. transcutaneous, percutaneous) could produce different effects through their different mechanisms, which means that there are many variables to take into account when considering the effectiveness of one type of ES compared to another and no conclusions could be drawn based on the identified evidence.

- **Is ES with non-implanted devices better than other conservative treatments?** Moderate-quality evidence suggests that ES is more effective than pelvic floor muscle training (PFMT) in improving OAB symptoms. It is very uncertain whether ES is more effective than PFMT in improving UUI or OAB-related QoL.

- **Is ES with non-implanted devices better than drug therapy?** Moderate-quality evidence suggests that ES may be more effective than drug therapy in improving OAB symptoms, but for improving UUI and OAB-related QoL there was no evidence to suggest a difference.

- **Is ES with non-implanted devices added to other treatments better than other treatments alone?** We do not know if adding ES to PFMT, to behavioural therapy or to drug therapy leads to improvement in OAB symptoms or OAB-related QoL. There is very limited evidence to suggest that adding ES to PFMT may reduce UUI episodes.

- **Is ES safe?** There may be a lower risk of adverse effects with ES than placebo, sham treatment, oxybutynin or tolterodine.

- **Is ES cost-effective?** We cannot tell from the identified evidence. It is important to consider cost-effectiveness in any intervention to assist policymakers, healthcare providers and people with OAB in decision-making with regard to treatment. Future trials should include a measure of costs from both the provider and patient perspective, equated to a meaningful patient-centred outcome.

Implications for research

This review highlights the urgent need to conduct well-designed trials in this field. It is evident from our findings that the current evidence base is inadequate to answer fully the question of the effectiveness of ES with non-implanted electrodes for overactive

bladder, therefore it is important that future trials should be adequately powered and should measure the following.

- Subjective perception of symptomatic improvement
- Head-to-head comparisons of different types of ES
- Cost-effectiveness of ES compared to other active treatments
- Clinically meaningful measurement of OAB-related QoL
- Adverse effects data

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CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Aaronson 1995

Methods	Study design: RCT Period: October 1992-January 1994
Participants	N: 47 randomised and analysed. Age: 24-82 years Sex: women Inclusion criteria: genuine stress urinary incontinence (GSUI) or detrusor instability (DI) Exclusion criteria: not reported
Interventions	For detrusor overactivity incontinence women only (DO) A (n = x): probanthine B (n = x): ES 2nd RCT in people with GSUI C (n = x): PFMT D (n = x): ES
Outcomes	Cure - defined as cessation of incontinence. A: not reported B: not reported Improvement defined as reduction in frequency of voids per 24 hours by $\geq 50\%$, or ≤ 10 voids per 24 hours, or decrease number of pads per 24 hours by $\geq 50\%$ Cured or improved: A (n = x): unclear (50% 'responded well'), B (n = x) 69%, C (n = x) 44%, D (n = x) 66%
Notes	No useable data Study authors contacted for further data

Risk of bias

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported

Aaronson 1995 (Continued)

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not reported
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Abdelbary 2015

Methods	Study design: RCT Setting: Egypt Follow-up: 6 weeks' treatment, 6 months' follow-up
Participants	N: 315 randomised, 300 analysed Mean (SD) age: A, 49.7 (6.0); B, 47.7 (6.0); C, 48.0 (6.0) Sex: women Inclusion criteria: ≥ 40 years, no evidence of urinary tract infection, no SUI, no previous history of anti-incontinence or pelvic surgery or anti-incontinence drugs (within 3 months), and no history of bladder malignancy Exclusion criteria: not reported
Interventions	A: (n = 105) vaginal ES twice weekly for 12 sessions B: (n = 105) local vaginal oestrogen 0.625 mg/g (Premarin), 2 g daily for 6 weeks C: (n =) ES plus local vaginal oestrogen
Outcomes	Voids per day (mean, SD, N) End of treatment: A 4.7 (0.8), 105. B 5.0 (0.9), 105. C 5 (0.8), 105 3 months: A 5.0 (1.0), 105. B 5.3 (0.9), 105. C 5 (0.8), 105 6 months: A 6.6 (1.5), 105. B 5.0 (0.8), 105. C 5 (0.8), 105 Voids per night (mean SD, N): End of treatment: A 0.9 (0.7), 105. B 1.4 (0.8), 105. C 0.5 (0.5), 105 3 months: A 1.1 (0.9), 105. B 1.5 (0.8), 105. C 1 (0.9), 105 6 months: A 2.2 (0.9), 105. B 5.0 (0.8), 105. C .5 (0.8), 105 Incontinence episodes (mean SD, N) End of treatment: A 0.1 (0.3), 105. B 0.4 (0.6), 105. C 0.07 (0.25), 105 3 months: A 0.1 (0.3), 105. B 0.5 (0.6), 105. C 0.09 (0.28), 105 6 months: A 0.4 (0.6), 105. B 0.4 (0.6), 105. C 0.09 (0.28), 105 Urgency episodes (mean SD, N) End of treatment: A 2 (0.7), 105. B 4 (1.3), 105. C 1.4 (0.7), 105 3 months: A 2.7 (1.0), 105. B 4.5 (1.5), 105. C 1.6 (0.9), 105 6 months: A 4.7 (1.3), 105. B 4 (1.3), 105. C 2 (0.8), 105 QoL score (higher score = greater severity, instrument not reported) (mean SD, N) End of treatment: A 2.8 (2), 105. B 5 (1.8), 105. C 2.9 (2.2), 105 3 months: A 4 (1.7), 105. B 6 (2), 105. C 3.7 (2.5), 105 6 months: A 7.6 (3), 105. B 6 (2), 105. C 4.8 (1.9), 105 Functional bladder capacity (ml) (mean SD, N) End of treatment: A 343.8 (46), 105. B 310 (40.6), 105. C 361 (40), 105 Detrusor overactivity (mean SD, N) End of treatment: A 27/105. B 32/105. C 12/105
Notes	

Abdelbary 2015 (Continued)

<i>Risk of bias</i>		<i>Risk of bias</i>
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"computer-generated random numeric table"
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not possible to blind participants, other blinding not reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No differential withdrawal, no explanation for withdrawals, no indication on how missing data were dealt with in analysis

Alves 2015

Methods	Study design: RCT Setting: Brazil Follow-up: 4 weeks' treatment
Participants	N: 28 randomised Sex: women Inclusion criteria: female, ≥ 60 years with likely urinary dysfunction, identified by a score ≥ 8 points on OAB-V8 questionnaire Exclusion criteria: urinary infection, identified by urine test, history of treatment for OAB and hormone replacement therapy in the last six months, prior surgery to treat UI, neurological diseases base, genital-urinary cancer history, complaints of pain in the lower abdomen for more than six months, prior pelvic irradiation, genital prolapse above third degree of Baden and Walker scale, use of cardiac pacemakers, metal implants in foot and right ankle region, inability to respond to questionnaires properly and abstentions to treatment
Interventions	A: (n = 15) tibial nerve stimulation (TNS). 8 sessions (2 x 30-minute sessions per week) F = 10 Hz, T = 200 μ s. Sensory threshold, activating superficial cutaneous nerve fibres with larger diameter B: (n = 13) TNS 8 sessions (2 x 30-minute sessions per week). F = 10 Hz, T = 200 μ s. Motor threshold, non-painful contraction was induced and "the stimulation can simply make pain relief in the same way that sensory stimulation level (blocking activation of the peripheral or central inhibition."

Outcomes	<p>All scores are higher score = greater severity</p> <p>ICIQ-OAB score (mean SD, N) A 4.46 (2.66), 15. B 4.53 (3.07), 13</p> <p>Bother of daytime frequency (mean SD, N) A 3.20 (2.59), 15. B 3.38 (3.17), 13</p> <p>Bother of nocturia (mean SD, N) A 3.40 (3.26), 15. B 1.84 (2.51), 13</p> <p>Bother of urgency (mean SD, N) A 4.00 (2.59), 15. B 3.53 (3.59), 13</p> <p>Bother of urgency incontinence (mean SD, N) A 2.73 (3.65), 15. B 4.38 (4.29)</p> <p>Micturitions per 24 h (mean SD N) A 8.33 (2.52), 15. B 7.89 (2.64), 13</p> <p>Nocturia episodes (mean SD, N) A 1.26 (1.21), 15. B 1.05 (1.01), 13</p> <p>Urgency episodes (mean SD, N) A 0.79 (0.96), 15. B 0.58 (0.65), 13</p> <p>Urgency incontinence episodes A 0.33 (0.57), 15. B 0.84 (1.39), 13</p>
Notes	

<i>Risk of bias</i>		<i>Risk of bias</i>
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"randomisation of two groups"
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"blind assessment and comparison between groups"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"blind assessment and comparison between groups"
Incomplete outcome data (attrition bias) All outcomes	Low risk	No withdrawals reported

Amaro 2006

Methods	<p>Study design: RCT</p> <p>Multicentre or single-centre: single-centre</p> <p>Setting: Botucatu Medical School, Unesp - Univ Estadual Paulista, Brazil</p> <p>Period: January 2001-February 2002.</p> <p>Sample size: "Based on outcome measurements with no numerical variable...the statistical test sample size had previously been established as at least 40 women."</p> <p>Follow-up: 7-week treatment period, follow-up appointments one month after end of treatment</p>
Participants	<p>N: 40 randomised</p> <p>Mean age:</p> <p>A: 49.0 (range 41-79)</p> <p>B: 47.0 (range 40-78)</p> <p>Sex: women</p> <p>Inclusion criteria: symptoms of predominant urge incontinence</p> <p>Exclusion criteria: vaginal prolapse greater than grade II (Baden), retention complaint or obstruction diagnosis during USD, urinary infection, changes in cutaneous sensitivity, metal implants, and neurological complaints</p>
Interventions	<p>A: (n = 20): electrostimulation. 3 x 20-min sessions per week on alternate days over a 7-week period, performed using Dualpex Uro996. Frequency at 4 Hz, a 2-to 4-s work rest cycle and a 0.1 us pulse width. The bipolar square wave could be delivered over a range of 0-100 mA. Intensity was controlled according to participant discomfort level feedback</p> <p>B: (n = 20): sham. Same type of vaginal probe with wires disconnected so no electrical energy was supplied</p>
Outcomes	<p>Number of micturitions per 24 h (mean, SD*, N): A: 7.0 (1.78), 20; B: 7.5 (1.78), 20 P = 0.38</p> <p>1 hour PAD test (g): A: 1.05; B: 1.13</p> <p>Number of participants with UUI: A: 3/20 (15%), B: 6/20 (31.5%)</p> <p>Number of participants 'satisfied': A: 16/20 (80%), B: 13/20 (65%)</p> <p>Reduction in "analog wetness sensation": A: 31.5%. B: 26.9%</p> <p>Reduction in "analog discomfort sensation": A: 39.7%; B: 24.5%</p> <p>Pelvic floor muscle strength measured with portable perineometer (Dynamed) (cmH₂O) (mean, SD, N): A: 53.8 (18.6), 20; B: 46.8 (12.5), 20</p> <p>Vaginal cone weight test (g) (mean, SD, N): A: 4.0 (1.3), 20; B: 2.0 (1.1), 20</p>
Notes	<p>No SDs reported (except for 2 outcomes).</p> <p>*SD calculated by FS using means and P value</p> <p>No evidence of source of data in review</p> <p>Information received from study authors</p>

Risk of bias

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"In the Randomization the participants in each groups were raffled" (from correspon-

Amaro 2006 (Continued)

		dence with author)
Allocation concealment (selection bias)	Unclear risk	“the allocations were concealed because a nurse, at each session, was responsible for carrying out the random assignment of patients” (from correspondence with author)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants blinded. ES sessions carried out by physiotherapist and outcome assessment carried out by different personnel (from correspondence with author)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	ES sessions carried out by physiotherapist and outcome assessment carried out by different personnel (from correspondence with author)
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No withdrawals reported, % given without denominators, unclear if all participants present for follow-up

Arruda 2008

Methods	<p>Study design: RCT</p> <p>Multicentre or single-centre: single-centre</p> <p>Setting: Department of Urogynecology, Federal University of São Paulo, Brazil</p> <p>Period: August 2001-September 2005</p> <p>Sample size: justified (a power calculation was performed based upon a predicted minimum difference of eight episodes of urinary leakage, with a significance level of 0.05, yielding a power estimate of 90% for a sample size of 20 women per each group)</p> <p>Follow-up: 12 weeks' treatment, 1-year follow-up</p>
Participants	<p>N: 77 randomised, 64 analysed</p> <p>Mean age (SD): A 51.9 (13,4); B 51.5 (11,4); C 54.1 (11,6)</p> <p>Sex: women</p> <p>Inclusion criteria: OAB and DO</p> <p>Exclusion criteria: persistent urinary tract infection, inability to comply with regular follow-up visits, current pregnancy, postvoid residual volume greater than 100 mL, contraindications to anticholinergic therapy, cardiac pacemaker, type III stress urinary incontinence, uncontrolled metabolic conditions or indwelling catheterisation, using medications including anticholinergic drugs, calcium antagonists, β agonists, dopamine agonists, striated muscle relaxants, or oestrogens</p>
Interventions	<p>A: (n = 26): oxybutynin immediate release 5 mg twice daily for 12 weeks</p> <p>B: (n = 25): ES. Ambulatory stimulation applied vaginally by a physiotherapist, twice a week, for 20 min at each session using 1 ms of intermittent biphasic waves, frequency 10 Hz. Current intensity ranged from 10-100 mA, according to participant tolerance to the procedure</p>

	C: (n = 26): exercises (PFMT), performed twice a week in orthostatic, sitting, and supine positions. Each session had a total duration of 45 minutes. A total of 40 fast (2 and 5 s) and 20 sustained (10 s) contractions with an equal period of relaxation between them were administered by a physiotherapist in the outpatient setting
Outcomes	<p>Participants with urgency symptoms (subjective) A 8/22. B 10/21. C 9/21</p> <p>Participants not satisfied (subjective) 12 weeks: A 5/22. B 10/21. C 5/21 1 year: A 12/22. B 17/21. C 12/21</p> <p>Participants not cured (objective evaluation: urodynamics) A 14/22. B 9/21. C 10/21.</p> <p>Number of leakage episodes per 24 hours (mean, SD, N) A 7 (10.6), 22. B 7.9 (13.7), 21. C 7.8 (15.3), 21</p> <p>Number of micturitions per 24 hours (mean, SD, N) A 6.4 (1.6), 22. B 7.9 (2.63), 21. C 7.1 (2.1), 21</p> <p>Number of nocturia episodes per night (mean, SD, N) A 0.9 (0.8), 22. B 1.2 (1.3), 21. C 1.0 (1.1), 21</p> <p>Number of pads used per 24 hours (mean, SD, N) A 0.9 (1.5), 22. B 0.9 (1.7), 21. C 0.8 (1.3), 21</p> <p>Post micturition residual volume, mL (mean, SD, N) A 4.8 (9.4), 22. B 1.1 (2.5), 21. C 2.1 (3.5), 21</p> <p>Maximum cystometric capacity, mL (mean, SD, N) A 517.3 (191.7), 22. B 436.7 (178.7), 21. C 489.0 (141.3), 21</p> <p>Volume at FDV (mean, SD, N) A 157.3 (63.8), 22. B 123.8 (59.0), 21. C 137.6 (76.7), 21</p> <p>*Involuntary detrusor contraction volume, mL (mean, SD, N) A 188.6 (183.2), 22. B 173.3 (112.4), 21. C 114.3 (154.2), 21</p> <p>Involuntary detrusor contraction maximal pressure, mmH₂O (mean, SD, N) A 19.6 (20.9), 22. B 22.4 (6.6), 21. C 17.2 (25.5), 21</p> <p>Adverse effects Dry mouth: A 16/22. B, C not reported Difficulty on micturition: A 2/22. B, C not reported Dizziness: A 1/22. B, C not reported Blurred vision: A 1/22. B, C not reported Constipation: A 1/22. B, C not reported</p>
Notes	<p>*Value for group B reported in paper as 73.3; queried with author and correct value is 173.3</p> <p>We contacted the main study author to clarify methodological aspects of the study and request further information</p>

<i>Risk of bias</i>		<i>Risk of bias</i>
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"blindly randomized to one of the three treatment groups" Additional information from study au-

Arruda 2008 (Continued)

		thor correspondence: "Patients were randomised using a table of random numbers generated by a statistical program on a computer"
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	High risk	Additional information from author correspondence: "patients and researchers knew to which group the patients belonged"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Additional information from author correspondence: "Data were analysed by a statistician who did not know which group the patients belonged to."
Incomplete outcome data (attrition bias) All outcomes	Low risk	No differential withdrawal. Adequate explanation for withdrawals

Barroso 2002

Methods	Study design: RCT Setting: Department of Gynecology and Obstetrics Hospital das Clínicas de Porto Alegre, Rio Grande do Sul, Brazil Period: March 2000-August 2001 Sample size: 36 participants for a power of 80% and a 2:1 ratio Follow-up: 6 months
Participants	N: 36 Sex: women Mean (SD) age: A: 54 (9.5); B: 56 (12.2) Inclusion criteria: SUI, UUI or MUI, understanding and signing a letter of informed consent Exclusion criteria: prolapse or first degree urogenital prolapse, intrinsic sphincter deficiency, cardiac pacemaker, pregnancy or in the puerperal period, post-menopausal climacteric's symptoms and signs of urogenital atrophy, genitourinary surgery during the previous 6 months, previous ES of the pelvic floor, medication chronically known to possibly change voiding function, change in the dose or if they had begun to use a new medication in the last 3 months, or during treatment with ES, reflex urinary incontinence, paradoxical urinary incontinence, urinary incontinence of intravesical obstructive factor, urinary incontinence caused by overflow, characterised by the presence of a large urinary residual volume, urgency incontinence treated with medication during last 3 months, or during treatment with ES; reflex urinary incontinence (clear presence of neurological lesions); paradoxical urinary incontinence (presence of intravesical obstructive factor); urinary incontinence caused by the presence of a large urinary residual volume; people with urge incontinence who had treatment with medication during last 3 months

Interventions	<p>A: transvaginal ES (n = 24). Battery-powered, portable device, 20 or 50 Hz, a pulse width of 300 ms, with asymmetrical biphasic pulses, an adjustable current intensity (0-100 mA), a 1 s rise time, sustained for 5 s and resting for 5 s. A time-of-use counter allowed a check on patient compliance with treatment, because it stored in the microcontroller memory the total time of use, corresponding to the time during which current actually circulated through the electrodes. Two 20-min sessions per day while recumbent, for 12 weeks</p> <p>UI or MUI: equipment programmed for 20 Hz Stress urinary incontinence: equipment programmed for 50 Hz UI or MUI: equipment programmed for 20 Hz SUI: equipment programmed for 50 Hz</p> <p>B: sham (n = 12). Identical equipment and regimen but without electrical stimulus</p> <p>All participants requested to complete 3-day voiding diary at beginning of study and again at 12 weeks' follow-up</p>
Outcomes	<p>Number of participants cured/improved at 12 weeks A: 21 (88%) B: not reported</p> <p>Number of voids per 24 hours (mean (SD) N) A: 7.5 (2.0) 24; B: 10.5 (2.8) 12</p> <p>Number of nocturia episodes (mean, SD, N) A: 1.1 (0.5), 24; B: 2.3 (0.9), 12.</p> <p>Number of incontinence episodes per 24 h (mean, SD): A: 1.3 (1.0) 24; B: 3.0 (0.9) 12</p> <p>Number of uninhibited contractions per 24 h (mean, SD): A: 2 (8), 24; B: 4 (not reported)</p> <p>Maximum bladder capacity (mean, SD, N) A: 425.0 mL (97.8), 24; B: 316.7 mL (71.8), 12</p>
Notes	<p>Compliance: 60 h of equipment use was expected. A: 46 hours B: 40 hours</p> <p>We contacted the main author of the study to clarify methodological aspects of the study and request further information. Awaiting reply</p>

Risk of bias**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"The participants were randomized before the study by drawing lots"
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"The participants were randomized before the study by drawing lots, with no participation by the examiner who, at the start of the treatment of each patient, was already receiving the group determined by randomization (study or control). Likewise

Barroso 2002 (Continued)

		the patients did not know into which group they had been placed (active or placebo) . The patients in the control group were evaluated at different times from the study group, to avoid any exchange of information among them”
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Urodynamic evaluations carried out by examiner unaware of the study. Participants also unaware of intervention allocated
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No withdrawals reported

Bellette 2009

Methods	Study design: RCT Multicentre or single-centre: single-centre Setting: Female Urology Clinic of the Hospital das Clínicas at Campinas (HC/UNI-CAMP), Brazil Follow-up: 4 weeks
Participants	N: 37 randomised and analysed Mean age: 47.73 (10.90) Sex: women Inclusion criteria: 18-85 years, symptoms of OAB for > 6 months, voiding frequency > 8 micturitions daily, episodes of nocturia and/or urgency Exclusion criteria: pregnancy, neurological problems, accentuated dystopias (stages II and III in the definitions of ICS), urinary tract infection and urinary stress incontinence
Interventions	A: (n = 21): ES. Transcutaneous posterior tibial nerve stimulation. 8 sessions with Duplex device 961, 30 min twice a week B (n = 16) sham. Electrodes placed without electricity
Outcomes	Participants with urgency A 9/21. B 10/16. Frequency of micturitions (mean, N)* A 8.29, 21 B 10.55, 16 Decrease in frequency and urgency A 62.5%. B 42.8% (P < 0.05) OAB-Q severity score A 31.72 (18.25), 21. B 51.21 (32.11), 16 OAB-Q total score A 83.99 (16.99), 21. B 66.63 (25.06), 16 Nocturia episodes A 1.14 (1), 21. B 2.06 (1.2), 16
Notes	*Contacted study author to ask for SDs, no reply. Estimated SD used in meta-analysis

<i>Risk of bias</i>		<i>Risk of bias</i>
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"The randomization process was made by the FCM's statistics department"
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	High risk	"The evaluations were carried out by the investigator or the physiotherapist, and treatment was performed by the same person who evaluated the patient, thus creating a bond with the physiotherapist."
Blinding of outcome assessment (detection bias) All outcomes	High risk	"The evaluations were carried out by the investigator or the physiotherapist, and treatment was performed by the same person who evaluated the patient, thus creating a bond with the physiotherapist."
Incomplete outcome data (attrition bias) All outcomes	Low risk	All randomised participants included in analysis. "All women were submitted to eight sessions of therapy, all the questionnaires were completed and none of the women failed to attend the sessions more than 3 times. The reasons for missing sessions were very variable, but did not alter the results of the study."

Berghmans 2002

Methods	<p>Study design: RCT</p> <p>Multicentre or single-centre: single-centre</p> <p>Setting: hospital and private clinic (University Hospital Maastricht, Department of Urology, the Netherlands)</p> <p>Sample size: a level of significance of 95%, a power of 80%, an expected dropout rate of 10%, and an expected improvement of bladder overactivity status of treatment groups in comparison with non-treatment group, expressed as a decrease of approximately 30% in the Detrusor Activity Index (DAI), 20 participants in each of the 4 groups had to be recruited. Therefore, the intended sample size was set on 80 people</p> <p>Follow-up: unclear (9 weeks?)</p>
Participants	<p>N: 80 randomised, 68 participated and analysed (12 excluded as randomised 'erroneously')</p> <p>Mean (SD) age:</p> <p>A: 50.5 (11.8)</p>

	<p>B: 55.6 (14.8) C: 61.9 (13.5) D: 52.3 (15.4) Sex: women Inclusion criteria: Detrusor Activity Index 0.5 or greater; > 18 years, female, drug-free interval of at least 4 weeks before start of the study for the following drugs: anticholinergic, beta sympathicomimetic, alpha-blocker and psychopharmacological agents Exclusion criteria: mechanical intravesical obstruction, urinary calculus, repetitive symptomatic UTI (> 3 x per year), colpitis, clinical evidence of disordered action of heart (Lown III), pacemaker, pregnancy of lactating period, inability to comply with follow-up, treatment with physical therapies within 3 months before start of therapy, neurogenic or congenital disorders resulting in urinary incontinence (e.g. spina bifida), psychological disorders, irritation of the vagina (consult with the general practitioner and participant), poor adjustable diabetes mellitus: last HbA1C > 10, contra-indication for the use of an intravaginal or anal electrode, not able to understand Dutch, not able to travel</p>
Interventions	<p>A: controls (n = 14) B: Lower Urinary Tract Exercises (LUTE) (n = 18). 1 session per week for 9 weeks. Patient information and education; bladder training; specific PFMT aiming at detrusor inhibition reflex (DIR); toilet behaviour aiming at the aspects of the micturition process itself C: FES (n = 17). FES was applied vaginally through plug-mounted electrodes. The maximum level of the ES was 100 mA (I_{eff} = 6 mA), participant was instructed to use. The maximal characteristics were (frequency modulation of 0.1 s trains of rectangular biphasic 200 µs long pulses which varied stochastically between 4 and 10 Hz). Duration of treatment unclear D: FES + LUTE group (n = 19). Same LUTE programme plus an additional weekly FES session (for 9 weeks) Dropouts: A ?0, B 5, C 3, D 2</p>
Outcomes	<p>Detrusor Activity Index (DAI): urodynamic variables of ambulatory cystometry combined with data from micturition diary (i.e. condition-specific measure; 0-1 scale where higher = worse) (mean, SD): A 0.80 (0.26) 14, B 0.62 (0.33) 18, C 0.57 (0.33) 17, D 0.84 (0.27) 19</p>
Notes	

Risk of bias

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Randomization was done in blocks of four using opaque and sealed envelopes"
Allocation concealment (selection bias)	Low risk	"Randomization was done in blocks of four using opaque and sealed envelopes"

Berghmans 2002 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	Low risk	Besides the participant and the physical therapist all others, involved in randomisation, registration and evaluation were blinded for group allocation
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Besides the participant and the physical therapist all others, involved in randomisation, registration and evaluation were blinded for group allocation
Incomplete outcome data (attrition bias) All outcomes	Low risk	No differential dropout A total number of 10 women dropped out of the trial. 1 woman stopped before start of therapy, because she considered the burden of investigation too high. During the treatment period, 5 women stopped because of illness (2 in group II and 2 in group III or allegedly reasons of too much burden felt (1 in group IV) “Missing data in the set of post-treatment DAI-scores were substituted by post-treatment means of the empirical data according to the intention-to-treat principle.”

Boaretto 2011

Methods	Study design: RCT Multicentre or single-centre: not reported Setting: Brazil Period: August 2008-2010 Sample size: not reported Follow-up: 4 weeks
Participants	N: 73 randomised, unclear how many included in analysis Mean (SD) age: 61.3 (not reported) Sex: women Inclusion criteria: women with OAB Exclusion criteria: not reported
Interventions	A: (n = 22) PFMT. 12 sessions. Group exercises performed in sitting, standing and supine positions with 20 contractions of 2 s, 10 contractions of 5 s and 5 contractions every 10 s B: (n = 22) ES, pulse width 200 ms. Transcutaneous posterior tibial nerve stimulation (TPTNS). Frequency 10 Hz. 12 x 30-min sessions C: (n = 16) functional ES with vaginal electrode, pulse width 500 microseconds. Frequency 10 Hz. 12 30-minute sessions D: (n = 13) oxybutynin. 5 mg immediate release twice daily for 12 weeks

Boaretto 2011 (Continued)

Outcomes	Satisfaction A 91% (20/22). B 77% (17/22). C 69% (11/16). D 61.5% (8/13) (not satisfied: A 2/22. B 5/22. C 5/16. D 5/13.)
Notes	Data presented for urinary frequency, nocturia, urgency and urgency incontinence but not usable Unable to find contact details for study authors

Risk of bias *Risk of bias*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"randomized into four treatment groups"
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No withdrawals reported. Outcome data presented without denominators or SDs

Booth 2013

Methods	Study design: RCT Multicentre or single-centre: not reported Setting: UK Period: not reported Sample size: not reported Follow-up: 6 weeks
Participants	N: 30 randomised, 28 analysed Sex: men and women Mean age: 84.2 (10.0) Inclusion criteria: men and women > 65 in residential care home settings or sheltered accommodation with bothersome LUTS, urinary incontinence, faecal incontinence, or constipation; capacity to provide ongoing informed consent to participate Exclusion criteria: pacemaker in situ, leg ulcers or broken skin on lower limb, peripheral vascular disease, reduced/absent sensation at the electrode sites, moderate or severe cognitive impairment or learning difficulties, UTI on assessment, or clinical diagnosis of only SUI

Booth 2013 (Continued)

Interventions	A: (n = 15) PTNS. 2 x 30-min sessions per week for 6 weeks. Frequency 10 Hz and pulse width 200 ms in continuous mode The intensity level of the stimulation current range (0-50 mA) B: (n = 13) Sham. Same procedure with stimulation current reduced to 2 mA
Outcomes	Number of participants with no improvement in incomplete bladder emptying A 7/15, B 12/13 Number of participants with no improvement in voiding frequency A 4/15, B 7/13 Number of participants with no improvement in urgency A 4/15, B 9/13 Number of participants with no improvement in nocturia A 8/15, B 10/13 Number of participants with no improvement in weak urinary stream A 6/15, B 12/13 Number of participants with no improvement in intermittency A 10/15, B 11/13 Number of participants with no improvement in urinary straining A 9/15, B 12/13 Number of participants with no improvement in frequency of UI episodes A 8/15. B 11/13. Number of participants with no improvement in amount of urine leaked A 7/15. B 11/13. Number of participants with no improvement in interference with everyday life A 6/15. B 7/13. Number of participants with no improvement in constipation A 14/15, B 6/13 Number of participants with no improvement in bowel urgency A 11/15, B 12/13 Number of participants with no improvement in faecal leakage A 8/15, B 10/13 Reduction in AUASI score (median, IQR, N): A -7 (-8 to -3), 15. B 1 (-1 to 4), 13. (P < 0.001, Mann-Whitney U 16.5000, Z -3.742) Reduction in ICIQ-SF score (median, IQR, N): A 2 (0 to -6), 15. B 0 (-3 to 3), 13. (P = 0.132) Number of participants with no improvement in ICIQ-SF score A 5/15. B 7/13
Notes	Two participants had predominantly faecal incontinence.

Risk of bias

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"online randomization service"
Allocation concealment (selection bias)	Unclear risk	Not reported

Booth 2013 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants blinded. "Staff were blind to the group allocation."
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	"Fidelity to the protocol was high and 28 of the 30 participants completed the 12 session course, with two discontinued at session five because they developed infections"

Bower 1998

Methods	<p>Study design: RCT Multicentre or single-centre: single-centre Setting: Australia Period: January 1996-February 1997 Sample size: 40% volume increase and 35% decrease in maximum detrusor pressure 16 participants would be required per group for an 80% chance of detecting significant change Follow-up: immediately following single ES session</p>
Participants	<p>DO group: 48 randomised Urgency group: 31 randomised Mean (SD) age: overall 55.4 (16.8). DO group: 56.5 (16.8). Urgency group: 56.3 (16.9) Sex: women Inclusion criteria: DO or urgency Exclusion criteria: UTI, pregnancy, cardiac pacemaker, impaired cognition, neurogenic bladder dysfunction or cystocele beyond the introitus</p>
Interventions	<p>DO group A1 (n = 16) TENS - suprapubic placement Frequency 150 Hz, 200 ms pulse width B1 (n = 16) TENS - sacral placement Frequency 10 Hz, 200 ms pulse width C1 (n = 15) sham ES Urgency group A2 (n = ?) TENS - suprapubic placement Frequency 150 Hz, 200 microsecond pulse width B2 (n = ?) TENS - sacral placement Frequency 10 Hz, 200 mspulse width C3 (n = ?) sham ES</p>
Outcomes	<p>Vol. at FDV (mean, SD, N) A1 208.5 (132), 16. B1 154 (61), 16. C1 186 (77), 15 A2 180 (51). B2 111 (37). C2 138 (51) (n not reported) Max. cystometric capacity (mean, SD, N) A1 352 (144), 16. B1 305 (146), 16. C 313.5 (81), 15</p>

Bower 1998 (Continued)

	A2 291 (51). B2 241 (53). C2 285 (45) (n not reported)	
Notes		
Risk of bias		Risk of bias
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	“randomized to 3 groups”
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Low risk	“Both the supervising urogynaecologist and the patient were blind to group allocation”
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Data for urgency group not presented with numbers of participants, unclear how many in urgency group were randomised to each intervention

Brubaker 1997

Methods	<p>Study design: RCT</p> <p>Multicentre or single-centre: 4 centres</p> <p>Setting: Rush-Presbyterian-St.Luke's Medical Center, Chicago; Methodist Hospital, Indianapolis; Greater Baltimore Medical Center; and the Oregon Health Science University, Portland, USA</p> <p>Period: not reported</p> <p>Sample size: not reported</p> <p>Follow-up: 8 weeks</p>
Participants	<p>N: 148 enrolled, 121 randomised and analysed</p> <p>Mean (SD) age for all participants (not stratified by GSUI/DO): A 56 (11.9); B 57.7 (12.4)</p> <p>Sex: women</p> <p>Inclusion criteria: women with symptoms or urodynamic evidence of genuine stress incontinence or detrusor instability</p> <p>Exclusion criteria: urinary incontinence other than genuine stress incontinence, detrusor instability, or mixed incontinence. Age < 25 years, leakage episodes ≤ 3/weeks, inadequate cognitive ability (investigator judgment), infected urine, anatomic defect that precluded use of device, postvoid residual > 100 mL, implanted electric device, genitourinary surgery < 6 months previously, medication alteration ≤ 3 months previously, anticipated geographic relocation during study</p>

Interventions	For DO and mixed women only (n = 61): A (n = 33) transvaginal electric stimulation. Device: InCare Microgyn II. 20 Hz frequency, 2-second/4-second work-rest cycle, pulse width 0.1-us. Bipolar square wave could be delivered over a range of 0-100 mA. 20 min daily B (n = 28) sham. Identical device with disconnected wire so no electricity supplied. 20 min daily
Outcomes	Definition of cure: absence of abnormality as measured objectively by urodynamics Number of participants with DO: A 14/32, B 23/28 UI frequency 2.2 No improvement 2.3 Compliance 2.4
Notes	We contacted the main author of the study to request further information about further 3 publications of the same study. The study authors replied with information

<i>Risk of bias</i>		<i>Risk of bias</i>
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated random numbers, and used for stratified randomisation
Allocation concealment (selection bias)	Unclear risk	The study nurse at each site was responsible for carrying out the random assignment of participants in accordance with the randomisation scheme
Blinding of participants and personnel (performance bias) All outcomes	Low risk	The study nurse at each site was aware of the difference in probes, however the physician investigators were masked as to the type of vaginal probe provided to each participant
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Data sent to centralised data manager
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	“A total of 148 women were enrolled, 18% of whom withdrew from the study, leaving of a total 121 participants who completed the study. There was no statistically significant difference between the treatment groups with respect to withdrawal rates: 21% for the sham group and 14% for the stimulation group.” No explanation reported for withdrawals

Methods	Study design: RCT Setting: China Follow-up: 4 weeks' treatment
Participants	N: 100 randomised Inclusion criteria: neurogenic DO secondary to spinal cord injury Exclusion criteria: urinary tract infection, tumour of the urinary system, urinary calculus, vesicoureteral reflux confirmed by video urodynamics, bladder compliance > 10 mL/cmH ₂ O
Interventions	A (n = 50) PTNS using adhesive skin surface electrodes. Continuous, bi-polar square wave form with pulse duration of 200 μ s and stimulation frequency of 20 Hz. "The stimulator was controlled to determine the minimal current needed to induce a toe twitch. The intensity was then increased to the highest level tolerated by the participant who cannot induce lower limb muscle spasm in complete SCI patients and uncomfortable feeling on stimulating sites in incomplete SCI patients" B (n = 50) solifenacin succinate 5 mg per day
Outcomes	Leakage volume per day (ml) (mean SD, N) A 541.4 (47.5), 50. B 449.1 (89.2), 48 I-QoL (mean, SD, N) A 25.2 (1.0), 50. B 24.2 (1.0), 48 Adverse effects: A 0/50 B 5/50 (all dry mouth)
Notes	

Risk of bias**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"the patients were randomized into two groups"
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not possible to blind participants, other blinding not reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	No differential withdrawal, adequate explanation for withdrawals

Eftekhar 2014

Methods	Study design: RCT Multicentre or single-centre: single-centre Setting: Iran Follow-up: 12 weeks' treatment
Participants	N: randomised and analysed Sex: women Inclusion criteria: women with neurologic OAB confirmed by urodynamic diagnosis Exclusion criteria: not reported
Interventions	A: PTNS. 34-gauge needle placed 5 cm near internal malleolus. Sessions lasted 30 min B: 4 mg tolterodine daily for 3 months
Outcomes	Sexual function Subjective assessment of pelvic disorders
Notes	No useable data. Contacted study author 21-04-2016

Risk of bias

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"computer generated numbers"
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	High risk	"nor patients nor the physician were blinded to the patient's group"
Blinding of outcome assessment (detection bias) All outcomes	High risk	"nor patients nor the physician were blinded to the patient's group"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Before study began, 2 in PTNS group and 8 in the control group withdrew. No explanation reported

Finazzi-Agrò 2005

Methods	Study design: RCT Multicentre or single-centre: not reported Setting: Rome, Italy Period: not reported Sample size: not reported Follow up: not reported
Participants	N: 35 randomised and analysed Mean (SD) age: not reported Sex: 28 women, 7 men Inclusion criteria: OAB not responding to antimuscarinic therapy Exclusion criteria: not reported
Interventions	Says all cases treated in the same way as detailed in Stoller 1999 . A (n = 17, 14 F, 3 M) weekly PTNS B (n = 18, 14 F, 4 M) 3 times per week PTNS - every 2 days
Outcomes	Success = > 50% reduction in micturitions/24 hours OR If incontinent, > 50% reduction in UI episodes/24 hours A 11/17 (4/11 incontinent participants). B 12/18 (5/11 incontinent participants) Subjective improvement after 6-8 sessions A 17/17. B 18/18 Adverse effects A 0/17. B 0/18 Adverse effects: "None of the patients discontinued the treatment and all considered it tolerable and painless" Incontinence episodes per 24 hours (median, range, N) A 1 (0-3), 11. B 1 (0-3), 11 Micturitions per 24 hours (median, range, N) A 8 (5-15), 17. B 8 (6-18), 18 SF-36 (median, range, N) A 62 (24-81), 17. B 62 (25-80), 18 I-QoL (median, range, N) A 77 (35-100), 17. B 78 (33-100), 18
Notes	

<i>Risk of bias</i>		<i>Risk of bias</i>
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"randomly assigned"
Allocation concealment (selection bias)	Unclear risk	Not reported

Finazzi-Agrò 2005 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not possible to blind participants, other blinding not reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	All participants randomised seem to be included in analysis

Finazzi-Agrò 2010

Methods	<p>Study design: RCT</p> <p>Multicentre or single-centre: single-centre</p> <p>Setting: Tor Vergata University Hospital in Rome, Italy</p> <p>Period: February 2007-February 2009</p> <p>Sample size: with a sample size of 15 in each group this study had a power of 82.3% to yield a statistically significant result assuming that the difference in proportions was 0.45 (specifically 0.05 vs 0.50). This effect was selected because the magnitude was reasonable according to previously published findings. To account for a dropout rate of 10% the number of participants to be recruited was set at 17 for each group, 34 total</p> <p>Follow-up: 4 weeks</p>
Participants	<p>N: 35 randomised, 32 analysed</p> <p>Mean age (no SD reported): A 44.9; B 45.5</p> <p>Sex: women</p> <p>Inclusion criteria: female, urgency incontinence and urodynamically diagnosed detrusor overactivity incontinence, unresponsive to behavioural and rehabilitation therapy or antimuscarinics, able to give written, informed consent, 18 years of age or older, mentally competent and able to understand all study requirements, able to understand the procedures, advantages and possible side effects, willing and able to complete a 3-day voiding diary and I-QoL questionnaire, bladder capacity 100 mL or greater, no signs of neurologic abnormalities at objective examination; no history of neurologic pathology, no pharmacological treatment or pharmacological treatment unchanged for 30 days before beginning the study</p> <p>Exclusion criteria: pregnancy or intention to become pregnant during the study, active UTI or recurrent UTI (more than 4 per year), presence of urinary fistula, bladder or kidney stones, interstitial cystitis, cystoscopic abnormalities that could be malignant, diabetes mellitus, cardiac pacemaker or implanted defibrillator</p>
Interventions	<p>A (n = 18) PTNS. 12 sessions, 30 min, 3 times a week for 4 weeks. 34-gauge needle inserted percutaneously approx 5 cm cephalad to the medial malleolus of right or left ankle; surface electrode placed on medial aspect of ipsilateral calcaneus. Stimulation current (0-10 mA) with a fixed frequency of 20 Hz and a pulse width of 200 ms was increased until flexion of the big toe or fanning of all toes became noticeable. The current was set at the highest level that was tolerable to the participant</p> <p>B (n = 17) sham. Same schedule as PTNS group with stimulator briefly activated for</p>

	approximately 30 seconds so the participant felt a minor electrical sensation in the skin
Outcomes	<p>Number of participants with < 50% reduction in urgency incontinence episodes: A 5/17. B 18/18</p> <p>Number of incontinence episodes per 24 hours (mean, range, N): A 1.8 (1.2-2.2), 17. B 3.8 (3.0-4.5), 15</p> <p>Number of micturitions per 24 hours (mean, range, N): A 9.5 (8.4-10.7), 17. B 13.9 (11.3-16.5), 15</p> <p>Voided volume mL (mean, range, N): A 150.5 (126.8-174.3) 17. B 150.4 (125.8-175.1), 15</p> <p>I-QoL score (mean, range, N): A 69.9 (65.8-73.3), 17. B 70.6 (62.2-79.1), 15</p>
Notes	Contacted study author asking for SDs 27-11-14

<i>Risk of bias</i>		<i>Risk of bias</i>
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Computer-generated randomization list."
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Low risk	To verify participant blindness with respect to the assigned treatment after 3 sessions participants were asked which procedure they believed they received
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The results of the 2 groups were collected by 2 physicians, and analysed by a third physician and a statistician, both of whom were blinded regarding the procedure used in any single participant
Incomplete outcome data (attrition bias) All outcomes	Low risk	In the PTNS group 1 participant and in the placebo group 2 did not complete the study for personal reasons not related to the used technique. There remained 17 participants in the PTNS group and 15 in the placebo group. There was a loss of less than 20% so considered at low risk of bias

Methods	<p>Study design: RCT Multicentre or single-centre: single-centre Setting: USA Period: not reported Sample size: “to achieve a power of 0.80 with an estimated conventional large effect size ($f = 0.40$), we sought a sample size of 66 women (33 with urge UI and 33 with stress UI) with 11 participants per treatment by diagnosis group.” Follow-up: 8 weeks</p>
Participants	<p>N: 63 randomised, 48 analysed Mean (SD) age: UUI overall 61.0 (12.4), A 57.3 (12.5) B 66.5 (12.4) C 63.0 (14.5) SUI overall 55.1 (14.4), D 52.7 (15.0) E 63.6 (13.3) F 48.2 (16.2) Sex: women Inclusion criteria: SUI or UUI diagnosed by urodynamics or Medical, Epidemiological and Social Aspects of Aging (MESA) questionnaire, parous or nulliparous women 21 years or older, manual dexterity to dial the Liberty Electrical Stimulation Unit, fluent English, ≥ 3 incontinent episodes in 3 days. Women on HRT to maintain same oestrogen intake throughout study, women not taking hormones were asked not start an oestrogen regimen during study Exclusion criteria: zero score on Oxford pelvic floor muscle strength scale, denervation injury to the sphincters, anti-incontinence surgery, vaginal extent to extent that middle finger could not be inserted into vagina, BMI > 50, stage III/IV prolapse, pregnancy, neurologic conditions, any potentially confounding prescriptions drugs</p>
Interventions	<p>UUI A (n = 7) intravaginal ES plus PFMT. 14 sessions of 60 min PFMT exercises, then 30 min (12.5 Hz) at highest tolerable intensity Tampon-shaped Liberty ES device B (n = 8) PFMT alone. 60 minutes twice a week for 8 weeks C (n = 7) no active treatment SUI D (n = 14) as per group A E (n = 15) as per group B F (n = 12) as per group C</p>
Outcomes	<p>York Incontinence Perception Scale (YIPS) score (higher score is better) (mean, SD, N): UUI: A 41.2 (10.2), 6. B 47.0 (5.5), 6. C 28.8 (2.9), 6 SUI: D 46.4 (7.2), 9. E SUI 44.8 (6.3), 12. F 29.9 (2.2), 9 % change in YIPS score (mean, N): UUI: A 38.7%, 6. B 78.7%, 6. C -2.4%, 6 SUI: D 57.8%, 9. E SUI 37.0%, 12. F 2.0%, 9 Pelvic floor muscle strength, cm H₂O (mean, SD, N): UUI: A 27.0 (16.0), 6. B 47.2 (22.7), 6. C 34.3 (25.5), 6 SUI: D 36.7 (14.1), 9. E 32.5 (18.5), 12. F 26.1 (18.6), 9 % change in pelvic floor muscle strength, cm H₂O: UUI: A 8.9%, 6. B 155.1%, 6. C 1.2%, 6 SUI: D 119.8%, 9. E 49.8%, 12. F 5.2%, 9 Incontinence episodes in 3 days (mean, SD, N): UUI: A 3.0 (4.4), 6. B 2.3 (2.9), 6. C 7.8 (5.9), 6</p>

	<p>SUI: D 1.4 (1.6), 9. E 4.1 (4.2), 12. F 8.0 (5.6), 9 *incontinence episodes per day (mean, SD, N): A 1.0 (1.47), 6. B 0.8 (0.97), 6. C 2.6 (1.97), 6 D 0.5 (0.53), 9. E 1.4 (1.4), 12. F 2.7 (1.87), 9 % change in incontinence episodes in 3 days (mean, N): UUI: A -78.1%, 6. B -70.5%, 6. C -4.0%, 6 SUI: D SUI -83.7%, 9. E SUI -66.9%, 12. F SUI 50.9%, 9 Frequency of micturitions in 3 days (mean, SD, N): UUI: A 25.7 (9.4), 6. B 23.5 (5.9), 6. C 24.2 (10.4), 6 SUI: D 24.1 (10.4), 9. E 22.8 (8.3), 12. F 24.6 (8.9), 9 *frequency of micturitions per day (mean, SD, N): A 8.6 (3.13), 6. B 7.8 (1.97), 6. C 8.1 (3.47), 6 D 8.0 (3.47), 9. E 7.6 (2.77), 12. F 8.2 (2.97), 9 % change in frequency of micturitions in 3 days (mean, N): A -19.2%, 6. B -16.7%, 6. C 27.4%, 6 D -6.6%, 9. E -8.8%, 12. F -14.9%, 9</p>
Notes	<p>Different numbers of participants reported in thesis and journal article *Mean (SD) per day calculated from 3-day data: mean and SD divided by 3</p>

<i>Risk of bias</i>		<i>Risk of bias</i>
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"2 containers were prepared representing diagnosis groups (urge or stress incontinence). Each container held 33 slips of paper with 11 reading "e-stim," 11 reading "therapeutic exercise" and 11 reading "control." The office assistant offered the correct diagnostic container to the participant on the second visit."
Allocation concealment (selection bias)	Low risk	"2 containers were prepared representing diagnosis groups (urge or stress incontinence). Each container held 33 slips of paper with 11 reading "e-stim," 11 reading "therapeutic exercise" and 11 reading "control." The office assistant offered the correct diagnostic container to the participant on the second visit."
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"The primary researcher performed the outcome measures and administered the exercise programs. She was blinded to the participants' diagnosis as determined by the MESA but was not blinded to group allocation."

Firra 2013 (Continued)

Blinding of outcome assessment (detection bias) All outcomes	High risk	“The primary researcher performed the outcome measures and administered the exercise programs. She was blinded to the participants’ diagnosis as determined by the MESA but was not blinded to group allocation.”
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Some differential attrition: “of those who dropped out after randomization most (11/16) were in the exercise and stimulation group...there was no indication that discomfort was a factor.”

Franzén 2010

Methods	<p>Study design: RCT</p> <p>Multicentre or single-centre: 3 centres in Sweden</p> <p>Period: September 2001 and December 2005</p> <p>Sample size: the power analysis was calculated on the basis of the primary outcome measure, reduction of micturitions per 24 h. The minimal patient-perceivable improvement has been found to be a mean reduction of micturitions per 24 h equivalent to 20%. A reduction smaller than 20% would thereby not be of any significant clinical importance. There is a large uncertainty regarding the efficacy that can be expected for both ES treatment and drug treatment being 30% to 50%. Under the assumption that ES treatment would give a 70% reduction of symptoms and drug treatment (tolterodine) a 50% reduction and thereby give a difference between treatments of 20%, a Chi² test with a 2-sided significance level of 5% yielded a power of 80% for a sample size of 103 participants in each group. If the assumption was even bigger difference in efficacy, 70% for ES treatment vs. 40% for tolterodine, the sample size with an additional 10% to compensate for dropouts would be 55 participants in each group</p> <p>Follow-up: 24 months</p>
Participants	<p>N: 72 randomised and 61 analysed at 6 months, 52 analysed at 12 months, 46 at 24 months</p> <p>Sex: Women</p> <p>Mean (SD) age: A 55 (11); B 61 (12)</p> <p>Inclusion criteria: urgency incontinence symptoms for ≥ 3 months, increased frequency of micturition (≥ 8 micturitions per 24 hours), mean volume of urine voided per micturition ≤ 200 mL, total urine volume per 24 hours of < 3000 mL during a 48-hour bladder diary</p> <p>Exclusion criteria: Persistent UTI, post-void volume greater than 150 mL, history of neurological disease or dementia, pregnancy, contraindications to anticholinergic therapy, and a cardiac pacemaker. Participants were also excluded if they had used tolterodine or any other anticholinergic drugs in order to treat urgency/urge incontinence during the last 2 months or had received ES treatment within the last 3 years</p>
Interventions	<p>A (n = 33). ES vaginally and/or transanally with the MS-310 Device, MIC Rehab AB. Over 5-7 weeks, 10 stimulation treatments 1-2 times per week for 20 min with a</p>

	frequency of 5-10 Hz. The maximum ES was done with maximum tolerable intensity, which was adjusted up to the level of tolerable discomfort B (n =31) tolterodine SR 4 mg orally once daily for 6 months, with dose reduction allowed to tolterodine SR 2 mg daily if intolerable side effects occurred
Outcomes	Number of participants with moderate or severe urgency symptoms: A 10/33, B 12/31 Number of participants with no improvement in urgency symptoms: A 9/33, B 9/31 Change in frequency of micturition (mean, 95%CI (SD)*, N): 6 months: A -2.8 (-3.6 to -2.2 (1.96)), 30. B -3.2 (-4.1 to -2.4 (2.41)), 31 12 months: A -3.1 (95% CI, -4.0 to -2.1 (2.65)), n = 30. B -3.1 (95% CI, -4.3 to -1.9 (3.41)) n = 31 24 months: A -3.4 (-4.6 to -2.2 (3.35), n = 30. B -3.7 (-4.8 to -2.6 (3.12)), n = 31 Change in mean urine volume (mL) (mean, 95%CI (SD)*, N): A 54 (28-80 (72.66)), 30. B 55 (36-74 (53.97)), 31 Side effects: A 0/33 B** 9/30 dry mouth, 1/30 muscular pain KHQ: see Table 3. Various outcomes reported
Notes	*SD calculated by FS, using 95% CI **based on information received from study author 6-month data used in analysis because treatment was given for 6 months. Most other included studies provided data for end of treatment period N per treatment group at 12 and 24 months not given, assumed same as 6 months

<i>Risk of bias</i>		<i>Risk of bias</i>
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Randomization sequence was developed centrally, using a computer random number generator."
Allocation concealment (selection bias)	Low risk	"Assignment was enclosed in sequentially numbered opaque sealed envelopes by a person not involved in the study. Patients were included into the study and allocated to treatment group by the clinical staff responsible for the study at each participating center, by opening the lowest numbered envelope"

Franzén 2010 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	“Blinding of study personnel and participants to treatment assignment for the duration of the study was not possible due to the nature of the interventions.”
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	No differential dropout. Adequate explanation for withdrawals

Gaspard 2014

Methods	Study design: RCT Multicentre or single-centre: unclear Setting: Belgium Period: November 2010 - November 2012 Sample size: 15 per group required for 80% power to detect between-group difference Follow-up: 9 weeks' treatment, 6 months' follow-up
Participants	N: 31 randomised and analysed Mean (SD) age: A 43.5 (14.0). B 40.5 (9.5) Sex: women and men Inclusion criteria: EDSS score < 7 and, urgency symptoms, nocturia, urgency incontinence, urinary retention and/or weak stream, post-voiding symptoms such as incomplete bladder emptying sensation Exclusion criteria: acute MS episodes during the study, UTI, pelvic-perineal treatment in the past 6 months, pregnancy
Interventions	A (n = 16) PFME with biofeedback. One 30-min session per week for 8 weeks B (n = 15) ES + PFME. As per group A plus transcutaneous posterior tibial nerve stimulation. Frequency 10 Hz, 220 µs pulse width. One 30-min session per week for 9 weeks. Rectangular biphasic pulse. An external electrode was located 5 cm above the medial malleolus and 1 cm behind the tibia. The other electrode was positioned on the dorsum of the foot. 20 s on, 4 s off
Outcomes	Number of participants not satisfied: A 1/16. B 4/15 SF-Qualiveen total score (higher score = greater severity) (median, IQR, N): 9 weeks: A 1.000 (0.656, 1.719), 16. B 1.375 (0.625, 2.188), 15 6 months: A 1.313 (0.687, 1.625), 16. B 1.500 (0.344, 2.094), 15 *mean, SD, N 9 weeks: A 1.07 (0.65), 16. B 1.51 (0.83), 15. 6 months: A 1.21 (0.74), 16. B 1.39 (0.91), 15 Bladder hyperactivity score (median, IQR, N): 9 weeks: 5.00 (1.50, 8.00), 16. B 6.00 (2.5, 9.25), 15 6 months: 7.00 (3.50, 9.50), 16. B 5.00 (4.25, 7.75), 15

Gaspard 2014 (Continued)

	<p>*mean, SD, N 9 weeks: A 5.4 (3.67), 16. B 6.75 (3.91), 15 6 months: A 6.42 (3.9), 16. B 6.5 (3.45), 15 Daily urgency episodes (median, IQR, N): 9 weeks: A 1.2 (0.3, 5.0), 16. B 0.7 (0.2, 4.3), 15 6 months: A 2.0 (0.3, 2.7), 15. B 1.4 (0.0, 2.0), 15 *mean, SD, N 9 weeks: A 2.69 (3.02), 16. B 2.63 (3.08), 15 6 months: A 2.25 (2.53), 16. B 1.67 (1.64), 15 Adverse effects: A 0/16. B 0/15</p>
Notes	<p>Subcategories of Qualiveen scores available in paper Emailed study authors asking for means (SDs) 2 April 2015. Replied with data marked *</p>

<i>Risk of bias</i>		<i>Risk of bias</i>
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Participants were randomised"
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants not possible. Other blinding not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"Data analysis was blinded"
Incomplete outcome data (attrition bias) All outcomes	Low risk	No differential withdrawal. Adequate explanations for withdrawal not reported. Intention-to-treat analysis carried out

Gonzalez 2015

Methods	<p>Study design: randomised cross-over trial Setting: Chile Follow-up: switch modalities at 3 months, follow-up at 6 months</p>
Participants	<p>N: 82 randomised Sex: not reported Inclusion criteria: OAB symptoms Exclusion criteria: unable to comply with follow-up or had a history of neurological disease</p>

Interventions	A (n = 40 randomised and 31 analysed): transcutaneous posterior tibial nerve stimulation and behavioural therapy. Twice a week for 6 weeks B (n = 42 randomised and 37 analysed): behavioural therapy. One-to-one interview and assessment with a continence physiotherapist and written information After 3 months both groups switched treatment modalities for another 3 months
Outcomes	After 3 months' treatment: Visual analogue scale (VAS) (higher score = greater severity) (mean SD, N): A 5.81 (2.89), 31. B 7.50 (2.50), 37 Incontinence severity index (ISI) (higher score = greater severity) (mean, SD, N): A 5.15 (3.23), 31. B 7.38 (4.00), 37. Patient's Global improvement (PGI-I): A 85.7%. B 60.9% OAB-Q (higher score = greater severity) (mean SD, N): A 100.81 (41.50), 31. B 127.71 (40.64), 37

Notes

Risk of bias**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"computer generated sequence"
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not possible to blind participants
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	High risk	Withdrawals: A 9/40, B 5/42. No explanations for withdrawal

Methods	<p>Study design: RCT</p> <p>Multicentre or single-centre: multicentre</p> <p>Setting: USA</p> <p>Period: June 2011-December 2013</p> <p>Sample size: the sample size calculation was determined using the 2-sided Chi² test with a significance level of 5% and 80% power based upon the following assumptions: (1) proportion of responders at end of 12 weeks of treatment would be 50% in the active (test) group and 25% in the inactive (control) group; (2) a responder was defined as a subject who experienced decrease of $\geq 50\%$ in mean UUI episodes (leaks) between baseline and week 12 of the study; (3) 20% dropout rate</p> <p>Follow-up: 12 weeks</p>
Participants	<p>N: 163 randomised</p> <p>Mean age (SD): A 60.8 (14.3); B 62.4 (13.8)</p> <p>Sex: 138 women, 25 men</p> <p>Inclusion criteria: men and women, at least 18 years of age. Failure on primary OAB treatment, such as behaviour modification or fluid/diet management, AND at least 1 anti-cholinergic drug (unless participant was contra-indicated for anti-cholinergic use). Symptoms of OAB for at least 6 months</p> <p>Exclusion criteria: Dysfunctional voiding symptoms unrelated to OAB, such as clinically significant bladder outlet obstruction, and urinary retention (pvr > 100 cc). Morbidly obese, defined as having BMI > 40 kg/m². Stress predominant MUI. Neurological disease affecting urinary bladder function, including but not limited to Parkinson's disease, multiple sclerosis, stroke, spinal cord injury and uncontrolled epilepsy. Pelvic surgery (such as sub-urethral sling, pelvic floor repair) within the past 6 months. Intravesical or urethral sphincter Botulinum Toxin Type A injections within the past 12 months. Any neuromodulation therapy for OAB within the past 3 months. Failure to respond to previous neuromodulation therapy for OAB. Leading edge of any vaginal prolapse beyond hymenal ring. Prior peri-urethral or transurethral bulking agent injections for bladder problems within the past 12 months. Any skin conditions affecting treatment or assessment of the treatment sites. History of lower back surgery or injury that could impact placement of the patch, or where underlying scar tissue or nerve damage may impact treatment. Presence of an implanted electro-medical device (e.g. pacemaker, defibrillator, InterStim®, etc.), or any metallic implant in the lower back. Pregnant, nursing, suspected to be pregnant (by urine pregnancy method), or plans to become pregnant during the course of the study. Known latex allergies, or allergies or hypersensitivity to patch materials that will be in contact with the body (e.g. hydrogel, acrylic-based adhesive, polyurethane). Uncontrolled diabetes and/or diabetes with peripheral neuropathy. Current UTI or history of recurrent UTIs (> 3 UTIs in the past year). History of lower tract genitourinary malignancies within the last 6 months or any previous pelvic radiation. Any clinically significant systemic disease or condition that in the opinion of the Investigator would make the patient unsuitable for the study</p>
Interventions	<p>A (n = 80) 1 VERV electrode patch worn per week for 12 weeks</p> <p>B (n = 83) 1 sham electrode patch worn per week for 12 weeks</p>
Outcomes	<p>Change in urgency (urinary) incontinence episodes per day (median (IQR), N):</p> <p>A -3.7 (-4.7 to -1.0), 68. B -1.7 (-3.3 to -1.0), 75. P = 0.2191</p> <p>Change in urinary frequency per day (median (IQR), N):</p>

	<p>A -1.0 (-2.7 to 0.3), 80. B -1.3 (-3.0 to -0.3), 83. P = 0.2893</p> <p>Change in volume per void (mL) (median (IQR), N):</p> <p>A 1.0 (-26.6 to 23.5), 80. B 8.8 (-24.3 to 33.3), 83. P = 0.3387</p> <p>Change in urgency episodes (median (IQR), N):</p> <p>A -1.7 (-3.3 to 0.3), 80. B -1.7 (-3.3 to 0.3). P = 0.6557</p> <p>Change in OAB-symptom composite score (median (IQR), N):</p> <p>A -5.8 (-14.7 to 1.3), 80. B -8.0 (-15.3 to 0.3), 83. P = 0.4354</p> <p>Change in OAB-Q score (median (IQR), N):</p> <p>A 8.8 (1.6 to 20.0), 56. B 9.2 (-0.8 to 27.2), 66. P = 0.9918</p> <p>Percentage of participants with improvement in severity according to Patient Perception of Bladder Condition scale:</p> <p>A 53.7% of 80 (43/80). B 44.2% of 83 (37/83)</p> <p>Percentage of participants with overall improvement according to Treatment Benefit Scale:</p> <p>A 55.4% of 56 (31/56). B 42.4% of 66 (28/66)</p> <p>Percentage of participants with Improvement as measured by Overactive Bladder Satisfaction With Treatment Questionnaire:</p> <p>A 65.3% of 32 (21/32). B 57.6% of 34 (20/34)</p> <p>Percentage of participants improved as measured by clinicians using Clinical Global Impressions:</p> <p>A 23.2% of 80 (19/80). B 24.2% of 83 (20/83)</p> <p>Participants with adverse effects:</p> <p>A 30/80. B 29/82</p>
Notes	Emailed study author asking for means (SDs) 6 January 2015

<i>Risk of bias</i>		<i>Risk of bias</i>
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Allocation: randomized"
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"Masking: Double Blind (Subject, Investigator)"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"Masking: Double Blind (Subject, Investigator)"
Incomplete outcome data (attrition bias) All outcomes	Low risk	No differential dropout. Adequate explanation for withdrawals

Kosilov 2013

Methods	<p>Study design: RCT Multicentre or single-centre: not reported Setting: Russia Period: 2008-2010 Details of sample size calculation: not reported Follow-up: 1-month's treatment, 12 months' follow-up</p>
Participants	<p>N: 229 randomised, 208 analysed at 12 months Mean (SD) age: 66.3 (range 65-77) Sex: women Inclusion criteria: elderly women with urodynamic impairments and clinically confirmed OAB Exclusion criteria: not reported</p>
Interventions	<p>All groups: trospium 60 mg + solifenacin 40 mg for 6 weeks then one of the following, beginning 2.5 months after end of drug treatment: A (n = 59) drugs: trospium 60 mg + solifenacin 40 mg for a month B (n = 51) detrusor ES: an active electrode (50-70 cm²) above the pubis, and a passive electrode (150 cm²) in lumbosacral area, diadynamic current, frequency 20 Hz, modulation depth 50%-75%, intensity 20-40 mA, exposure 15 min, a course consisting of 15 procedures every other day C (n = 63) conservative treatment: laserpuncture by helium-neon laser (632.8 nm) at acupuncture points RP 6, RP 9, VC 2 within 1-1.5 min for each point every day, light guide output power, 2 mW, 25 procedures D (n = 56) placebo</p>
Outcomes	<p>Daily urinary incontinence episodes (mean, SD, N) 6 months: A 1.1 (0.7), 59. B 2.2 (0.9), 51. C 3.8 (0.8), 63. D 2.7 (1.1), 56 12 months: A 1.5 (0.9), 59. B 3.7 (1.3), 51. C 5.5 (1.4), 63. D 4.8 (2.4), 56 Volume at FDV, mL (mean, SD, N): 6 months: A 289.3 (37.6), 59. B 297.0 (45.3), 51. C 254.5 (49.1), 63. D 279.7 (54.8), 56 12 months: A 257.5 (28.9), 59. B 210.9 (28.7), 51. C 199.3 (49.4), 63. D 192.9 (28.9), 56 Volume at maximal desire to urinate, mL (mean, SD, N): 6 months: A 313.7 (47.1), 59. B 334.8 (38.3), 51. C 286.0 (36.6), 63. D 311.5 (51.7), 56 12 months: A 279.9 (33.8), 59. B 251.9 (42.9), 51. C 178.9 (29.0), 63. D 206.3 (SD missing), 56 Maximum bladder pressure, cmH₂O (mean, SD, N): 6 months: A 32.8 (6.0), 59. B 35.4 (9.3), 51. C 38.9 (7.8), 63. D 31.0 (7.9), 56 12 months: A 28.8 (4.7), 59. B 30.9 (4.9), 51. C 29.8 (6.3), 63. D 23.9 (5.4), 56</p>
Notes	

Risk of bias

Risk of bias

Bias	Authors' judgement	Support for judgement
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Kosilov 2013 (Continued)

Random sequence generation (selection bias)	Unclear risk	“we randomized 229 women”
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	14 participants withdrew due to side effects, 2 discontinued due to the lack of an immediate positive effect; and 2 withdrew for reasons unrelated to the treatment course Numbers of withdrawals not reported per treatment group.

Lima 2011

Methods	Study design: RCT Multicentre or single-centre: not reported Setting: not reported Period: not reported Sample size: not reported Follow-up: not reported	
Participants	N: 45 Sex: women Mean age: not reported Inclusion criteria: women with OAB symptoms Exclusion criteria: not reported	
Interventions	A (n = 16) PFMT B (n = 14) Intravaginal ES. Twelve 30-min sessions C (n = 15) Transcutaneous posterior tibial nerve stimulation. Twelve 30-minsessions	
Outcomes	Symptoms of urgency incontinence, defined as “absence, a little, more or less and much”	
Notes	No useable data	
<i>Risk of bias</i>	<i>Risk of bias</i>	
Bias	Authors’ judgement	Support for judgement

Lima 2011 (Continued)

Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not reported

Lin 2004

Methods	Study design: RCT Setting: China Follow-up: 4 weeks' maximum treatment
Participants	N: 60 randomised Sex: not reported
Interventions	A (n = 35) vaginal/anorectal ES, 8-70 mA, 20 min, 20-30 sessions B (n = 25) 2 mg tolterodine daily, 2-4 weeks
Outcomes	Cure rate: A 13/35. B 10/25 Improved: A 13/35. B 9/25 Satisfied or fairly satisfied: A 19/35. B 20/25 Side effects: Dry mouth: A 1/35. B 20/25 Uroschisis: A 0/35. B 2/25 Constipation: A 1/35. B 6/25 Blurred vision: A 0/35. B 1/25
Notes	Only partial translation available

Risk of bias

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"randomly divided"

Lin 2004 (Continued)

Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not possible to blind participants, other blinding unclear
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Unclear
Incomplete outcome data (attrition bias) All outcomes	Low risk	No differential withdrawal

Lo 2003

Methods	<p>Study design: RCT Multicentre or single-centre: single-centre Setting: Department of a Regional Hospital in Perth, Western Australia Period: not reported Sample size: 50 participants in each group would be sufficient to give 0.8 power at the 0.05 alpha level for two-sided alternative. Calculation of sample size was performed using the PASS statistical software (NCSS, Kaysville, Utah, USA). Parameters used in the calculations were derived from Jundt et al and Lamhut Follow-up: 4 weeks</p>
Participants	<p>N: 24 randomised and analysed Sex: women Mean age (SD): A (n =12) 52.1 (17.5) B (n = 12) 55.1 (15.1) Inclusion criteria: women, aged 20 years or older, with stress or UUI Exclusion criteria: altered mental state, urinary incontinence caused by problems other than stress or urge, transient incontinence, or severe disability requiring full assistance with all acts of daily living</p>
Interventions	<p>A (n = 12) PFMT. 12 sessions (3 per week for 4 weeks): 10 sets of 5 contractions with 30-s rest between each set. Then repeated after an hour B (n = 12) ITT plus PFMT. 12 sessions (3 per week for 4 weeks) of 50 pelvic floor contractions followed by ITT with Nemectrodyne 5 stimulator then another 50 contractions. 2 anterior flat electrodes placed over obturator foramen 1.5cm to 2 cm lateral to symphysis, 2 posterior electrodes placed medial to ischial tuberosities either side of anus. ITT was at highest tolerable frequency between 0-100 Hz for 15 min (session 1), then 30 min for sessions 2-12</p>
Outcomes	<p>Pelvic floor muscle strength measured with perineometer (mean, SD, N): A 9.55 (3.50), 12. B 8.08 (4.83), 12 Pad test (g) (mean, SD, N): A 1.25 (1.76), 12. B 9.00 (29.3), 12</p>

Lo 2003 (Continued)

	<p>Frequency (number of micturitions per day) (mean, SD, N): A 6.29 (2.2), 12. B 7.24 (2.62), 12</p> <p>Nocturia (number of nocturia episodes per night) (mean, SD, N): A 0.45 (0.86), 12. B 0.99 (1.04), 12</p> <p>Change in pelvic floor muscle strength (mean, SD, N): A 2.03 (2.10), 12. B 2.04 (2.47), 12. (P = 0.253)</p> <p>Change in pad test (g) (mean, SD, N): A -4.33 (8.37), 12. B -85.1 (150), 12. (P = 0.101)</p> <p>Change in frequency (mean, SD, N): A -0.07 (1.76), 12. B -1.81 (1.62), 12. (P = 0.006)</p> <p>Change in nocturia (mean, SD, N): A -0.49 (0.89), 12. B 0.86 (1.14), 12. (P = 0.199)</p> <p>No improvement in stop/start test, defined as change from unable to stop to being able to slow, or change from able to slow to able to stop: A 9/12. B 6/12 (P = 0.2)</p> <p>No improvement in urgency (not defined): A 8/12. B 4/12</p>
Notes	<p>We contacted the main author of the study to clarify methodological aspects of the study and request further information. Awaiting reply</p> <p>No useable data. Not stratified by stress/urgency incontinence</p>

<i>Risk of bias</i>		<i>Risk of bias</i>
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Participants were randomly allocated as soon as they gave written consent, using the sealed envelope method"
Allocation concealment (selection bias)	Unclear risk	Sealed envelopes
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants were not blinded due to the nature of the interventions but unclear if this would have effect on outcomes
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"Only the assessor but not the patients could be blinded."
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not reported

Lobel 1998

Methods	Study design: RCT Multicentre or single-centre: not reported Setting: USA Period: not reported Sample size: not reported Follow-up: 5 weeks' treatment then another 5 weeks' treatment if improvement observed after first 5 weeks, then follow-up six months after end of 10 weeks' treatment
Participants	N: 42 recruited, 37 randomised and analysed Mean (SD) age: 61 (17) Sex: women Inclusion criteria: DO Exclusion criteria: not reported
Interventions	A (n = 18) ES once a week for 5 weeks B (n = 19) ES twice a week for 5 weeks Medicon MS-210 with vaginal and anal probes
Outcomes	Incontinence episodes after 5 weeks (mean, N): 12 (37) Participants not improved after 5 weeks (N): 0 Participants satisfied enough to request no further treatment: 25% (9) Adverse effects: Discomfort: 16% (6/37) Leg tremor: 8% (3/37) UTI: 8% (3/37)
Notes	Data not presented by treatment - not useable

Risk of bias

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Randomized into two treatment groups"
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants not possible. Other blinding not reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	5/42 participants withdrew before treatment; no explanation reported. All participants treated included in analysis. No with-

Lobel 1998 (Continued)

drawals due to adverse effects

Manriquez 2013

Methods	Study design: RCT Setting: Chile Follow-up: 12 weeks' treatment
Participants	N: 56 randomised Sex: women Age: not reported Inclusion criteria: OAB according to ICI 2002 definition Exclusion criteria: not reported
Interventions	A (n = 28?) transcutaneous tibial nerve stimulation, twice a week with at least 48 h intervals for 12 weeks B (n = 28?) long release oxybutynin 10 mg
Outcomes	Frequency (mean? range, N): A 4 (2-7), 28. B 8 (1-13), 28 Urgency (mean? range, N): A 4 (1-6), 28. B 7 (4-15), 28 Urgency incontinence (mean? range, N): A 2 (0-3), 28. B 6 (1-11), 28 Daily pads (mean? range, N): A 0 (0-3), 28. B 4 (3-6), 28
Notes	Numbers randomised to each group not reported, assume equal numbers Table does not state if means or medians are reported.

Risk of bias

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"the randomization was made by permuted blocks"
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not possible to blind participants
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported

Manriquez 2013 (Continued)

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not reported
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Marques 2008

Methods	Study design: RCT Multicentre or single-centre: not reported Setting: Brazil Period: not reported Sample size: not reported Follow-up: 4 weeks
Participants	N: 43 randomised Mean (SD) age: not reported Sex: women Inclusion criteria: OAB Exclusion criteria: not reported
Interventions	A (n = ?) ES 30 min, twice per week for 4 weeks TENS, biphasic with 200 ms pulse duration, 10 Hz frequency, variation of intensity and frequency through one channel and two electrodes B (n = ?) unclear if sham or no active treatment: “same protocol but without electrical stimulation.”
Outcomes	Daytime frequency: difference between groups P = 0.0001 (in favour of intervention) Nocturia: difference between groups P = 0.0186 (in favour of intervention) Improvement in SUI: difference between groups P = 0.0273 (in favour of intervention) Urgency symptoms: difference between groups P = not significant Participants with no involuntary detrusor contraction: A 4/?. B 5/?
Notes	No useable data

Risk of bias

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	“randomized” ‘divided into two different groups”
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported

Marques 2008 (Continued)

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Unclear how many participants included in analysis
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Monga 2011

Methods	Study design: RCT Multicentre or single-centre: multi-centre Setting: UK Period: not reported Sample size: not reported Follow-up: 4 weeks
Participants	N: 74 randomised, 64 analysed Mean (SD) age: not reported Sex: men and women Inclusion criteria: ≥ 18 years, OAB symptoms ≥ 6 months, failure of OAB therapies such as behaviour modification and failure of \geq anti-cholinergic drug for OAB Exclusion criteria: not reported
Interventions	Patient-managed neuromodulation system (PMNS): transdermal amplitude-modulated signal through a patch applied to the skin, controlled by wireless handheld remote control. Patch worn for 4 weeks, placed by investigator initially A (n = 30) Investigator placement group. Participants returned every 7 days for patch removal and placement of a new patch on contra-lateral side B (n = 34) Subject placement group. Participants returned on day 7 for investigator observation of patch self-placement and replaced patch at home for the remaining 2 weeks
Outcomes	UUUI episodes (mean, SD, N): 2.2 (2.5), 64. % change from baseline in UUI episodes (mean, SD, N): -2.7% (3.1), 64. Change from baseline in UUI episodes (mean, SD, N): -47.8 (60.6), 64. Voiding frequency (mean, SD, N): 9.4 (2.7), 64. % change from baseline in voiding frequency (mean, SD, N): -1.9% (2.5), 64. Change from baseline in voiding frequency (mean, SD, N): -15.0 (19.1) Volume per void (mean, SD, N): 187.6 (75.0), 64. % change from baseline in volume per void (mean, SD, N): 8.2% (46.7), 64. Change from baseline in volume per void (mean, SD, N): 7.5 (26.4), 64. Urgency episodes (mean, SD, N): 7.8 (3.3), 64.

Monga 2011 (Continued)

	% change from baseline in urgency episodes (mean, SD, N): -2.2 (2.8), 64. Change from baseline in urgency episodes (mean, SD, N): -21.2 (28.6), 64.
Notes	Not useable - results not presented per treatment group Contacted study author requesting data per group 17 February 2015. Author responded “The device has been withdrawn. Probably doesn’t need to be in the review.”

Risk of bias		Risk of bias
Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	“subjects were randomized”
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not possible to blind participants.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No explanation reported for withdrawals. Data not presented per treatment group

Monteiro 2014

Methods	Study design: RCT Multicentre or single-centre: single-centre Setting: Brazil Period: February-June 2008 Sample size: “Pocock formula, with 47% of neurogenic OAB prevalence and decrease of 30% after treatment” Follow-up: 45 days’ treatment, 12 months’ follow-up
Participants	N: 24 randomised and analysed Mean (SD) age: A 65.1 (3.6). B 56.1 (10.9) Sex: men Inclusion criteria: ≥ 18 years with neurogenic OAB, with stroke occurring between 6 months and 3 years before recruitment Exclusion criteria: implanted cardiac pacemaker, UTI, bladder cancer, pre-existing urinary incontinence before stroke, or surgery in the urogenital region

Interventions	A (n = 12) ES of posterior tibialis nerve. Negative electrode was placed on the medial malleolus, and the positive electrode was placed 10 cm above the negative electrode, also on the medial side. The rhythmic flexion of the second toe during the stimulation determined the correct position of the negative electrode. The intensity level was set below the threshold that causes motor contraction because the participant should be comfortable and no pain should occur during the procedure. ES of the posterior tibialis nerve was performed for 30 minutes twice weekly over 12 sessions (45 days), with a frequency of 10 Hz and a pulse width of 200 µs in continuous mode B (n = 12) no active treatment for OAB. 12 stretching sessions of the lower limbs
Outcomes	Participants with no improvement in OAB symptoms: 12 months: A 0/12. B 9/12 Participants with urinary urgency: 45 days: A 7/12. B 10/12 12 months: A 6/12. B 9/12 Participants with UUI: 45 days: A 8/12. B 9/12 12 months: A 7/12. B 8/12 Participants with nocturnal enuresis: 45 days: A 0/12. B 2/12 12 months: A 0/12. B 2/12 Participants with nocturia: 45 days: A 5/12. B 9/12 12 months: A 1/12 B 6/12 Participants with increased daytime frequency: 45 days: A 3/12. B 11/12 12 months: A 0/12. B 9/12
Notes	

<i>Risk of bias</i>		<i>Risk of bias</i>
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	All participants were numbered sequentially from 1-24 and divided into 2 groups of 12 assigned to the treatment group
Allocation concealment (selection bias)	Unclear risk	All participants were numbered sequentially from 1-24 and divided into 2 groups of 12 assigned to the treatment group
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported. Impossible to blind participants
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported

Monteiro 2014 (Continued)

Incomplete outcome data (attrition bias) All outcomes	Low risk	All randomised participants included in analysis. One dropout. "One patient in the placebo group died after treatment, but was analyzed as if improved."
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Oldham 2013

Methods	Study design: RCT Multicentre or single-centre: not reported Setting: UK Period: not reported Sample size: the study was powered to detect a 3-point (common standard deviation of 6) between-group difference on the ICIQ-UI (scale of 0-21) with 80% power at a 5% level of significance Follow-up: 12 weeks
Participants	N: 124 randomised, 97 analysed Mean (SD) age: A 47.9 (8.9). B 48.2 (8.6) Sex: women Inclusion criteria: women, 18-65 years with self-reported SUI, UUI, or MUI Exclusion criteria: Pregnancy or a baby in the last 3 months. Recent abdominal surgery and previous or current active therapy for pelvic malignancy. Implanted pacemaker. Manual dexterity insufficient to place the device. Previous treatment for incontinence (including supervised PFME. Presence of a neurological condition such as multiple sclerosis or Parkinson's disease
Interventions	A (n = 64) ES. Pelviva device inserted like a tampon into the vagina. The stimulation programme was delivered using a duty cycle of 10-sstimulation followed by 10-s rest that runs for a period of 30 min, pre-programmed to automatically gradually ramp-up the intensity of stimulation over a 24-s period to reach a therapeutic level and switch off automatically after 30 min. During the 10 seconds 'on time' the device delivered 10 repeats of a short high intensity burst of 50 Hz stimulation immediately preceded by a doublet (125 Hz), superimposed on continuous low frequency 2 Hz stimulation Plus standardised advice about how and when to undertake PFME. These included 10 slow and controlled squeezing and lifting contractions and 10 quick contractions each repeated 3-4 times a day B (n = 60) unsupervised conservative treatment (no active treatment). Standardised advice about how and when to undertake PFME. These included 10 slow and controlled squeezing and lifting contractions and 10 quick contractions each repeated 3-4 times a day
Outcomes	Participants with no improvement in symptoms (i.e. same or worse ICIQ score): A 9/49. B 14/46 *A UUI 5/50. B 6/47. *A MUI 8/50. B 19/47. *A UUI+MUI 13/50. B 25/47 Participants with SUI, UUI or MUI A 94% (i.e. 46/49) B 100% (i.e. 46/46)

	<p>International Consultation on Incontinence Questionnaire - Urinary Incontinence (ICIQ-UI) score (higher score is increased severity) (median, range, N): A 6 (0-17), 49. B 9 (3-18), 46</p> <p>Leak frequency (0-5 scale, higher score is more leaks) (median, range, N): A 1 (0-4), 49. B 2 (1-4), 46</p> <p>Leak interference (0-10 scale, higher score is more interference) (median, range, N): A 3 (0-10), 49. B 4 (0-10), 46</p> <p>Leak amount (0-6 scale, higher score is greater amount) (median, range, N): A 2 (0-6), 49. B 2 (2-4), 46</p> <p>Adverse effects: A 0/49. B 0/46</p>
Notes	<p>*Outcome data not separated by SUI/UUI/MUI - contacted study author 3 February 2015, replied with supplementary data</p> <p>Femeda, the company responsible for developing and producing the Pelviva device was the trial sponsor. The sponsor was responsible for developing the Pelviva device, was the funder of the study, and was engaged in the development of the trial design. The sponsor has provided full access to the data and is fully informed of this publication process. The primary author (J.O.) takes full responsibility for the integrity of the data and accuracy of the data analysis</p>

<i>Risk of bias</i>		<i>Risk of bias</i>
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"subjects were assigned by a simple computer generated AB randomization list to either the exercise or Pelviva group."
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"Participants could not be blinded to the treatment group and were aware of the study hypothesis. Every care was taken to ensure the assessor remained blind to treatment allocation and participants were advised not to discuss their treatment with them."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"the assessor remained blind to treatment allocation"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No differential dropout. No explanations for withdrawals

Olmo Carmona 2013

Methods	<p>Study design: RCT Multicentre or single-centre: single Setting: Spain Period: not reported Details of sample size calculation: no previous data available for power calculation Follow up: 12 weeks</p>
Participants	<p>N: 24 randomised, 22 analysed Mean (SD) age: 60 (14.4) Sex: women Inclusion criteria: urgency incontinence, either men or women, 45-75 years, moderate-severe on ICIQ-SF and CACV, previous conservative treatment, at least 1 year of incontinence, willing to participate Exclusion criteria: neurological damage to tibial nerve, diseases of central nervous system, previous incontinence surgery, pacemaker, not well-controlled cardiac disease, pregnancy, important venous disease in the lower limbs, skin problems in lower limbs that would impede acupuncture, treatment with oral anticoagulants, acute infectious processes, psychiatric or cognitive impairments</p>
Interventions	<p>AWQ-104L Digital. 20 Hz, 320 μs. Square wave, current 0-10 mA. 30 mm x 1.5” needle A (n = 12) electrostimulation with SP 6 Sanyinjiao B (n = 12) percutaneous tibial nerve stimulation</p>
Outcomes	<p>Micturitions per day (mean (SD) N) A 7.73 (1.67), 11. B 8 (1.73), 11 Nocturia episodes (mean (SD), N) A 2.09 (1.92), 11. B 1.09 (1.51), 11 Urgency episodes per 24 h (mean (SD) N) A 5.09 (3.42), 11. B 3.09 (2.21), 11 Incontinence episodes per 24 h (mean (SD), N) A 4.55 (4.03), 11. B 1.64 (1.91), 11 B-SAQ score score (mean, SD, N) Symptoms: A 7.82 (1.83), 11. B 5.09 (2.17), 11 Complaints/problems: A 7.27 (2.24), 11. B 5.18 (2.56), 11 ICIQ-SF score (mean (SD), N) A 7.27 (2.24), 11. B 5.18 (2.56), 11</p>
Notes	

<i>Risk of bias</i>		<i>Risk of bias</i>
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation table
Allocation concealment (selection bias)	Low risk	Allocation carried out centrally by member of research team not involved in the inter-

Olmo Carmona 2013 (Continued)

		vention
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants can't be blinded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome assessors blinded - had no involvement in carrying out intervention
Incomplete outcome data (attrition bias) All outcomes	Low risk	No differential attrition

Orhan 2015

Methods	Study design: RCT Period: January 2010 and April 2011 Setting: not reported Sample size: not reported Follow-up: 12 weeks' treatment
Participants	N: 30 randomised Sex: not reported Age: not reported Inclusion criteria: people OAB in whom all conventional therapies had failed Exclusion criteria: not reported
Interventions	A: percutaneous posterior tibial nerve stimulation B: anticholinergic agent C: PTNS plus anticholinergic agent
Outcomes	A (n = not reported) percutaneous posterior tibial nerve stimulation B (n = not reported) anticholinergic agent C (n = not reported) PTNS plus anticholinergic agent
Notes	Urinary Distress Inventory (UDI-6) Incontinence Impact Questionnaire (IIQ-7) Over Active Bladder symptom scores (OABSS) "there was a statistically significantly higher improvement in PTNS and PTNS + ACA groups when compared to group 2" (B: anticholinergic agent alone)

Risk of bias

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"randomly divided into 3 groups."

Orhan 2015 (Continued)

Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not reported

Peters 2009

Methods	<p>Study design: RCT Multicentre or single-centre: 11 centres in the USA Setting: not reported Period: June 2006-September 2008 Sample size: the sample size used to support this analysis was based on the assumptions of significance level of 5%, power of 80%, and expected mean reduction in voids of 1.8 for tolterodine and 3.6 for PTNS based on previously published efficacy data. Secondary end points were analysed using 2-sided t tests with 95% CI. An independent biostatistician performed all analyses using SAS® Version 9.2. All voiding diary data were sent to the biostatistician for compilation and analysis Follow-up: 12 weeks</p>
Participants	<p>N: 100 randomised, 85 analysed Mean (SD) age: A 57.5 (15.2); B 58.2 (11.3) Sex: 94 women, 6 men Inclusion criteria: adults with OAB symptoms, with or without a history of previous anticholinergic drug use, with at least 8 voids per 24 h documented by history and physical and voiding diary Exclusion criteria: OAB pharmacotherapy within the previous month, primary complaint of SUI, demonstrated sensitivity to tolterodine or its ingredients, pacemakers or implantable defibrillators, excessive bleeding, urinary or gastric retention, nerve damage or neuropathy, uncontrolled narrow angle glaucoma, positive urinalysis for infection or pregnancy, or current pregnancy or planning to become pregnant during the trial</p>
Interventions	<p>A (n = 50) PTNS. 1 session per week for 12 weeks (no details reported on frequency, make/model of stimulator etc) B (n = 50) tolterodine. Extended-release 4 mg daily for 90 days (decreased to 2 mg if intolerability was experienced - 2 participants reduced to 2 mg)</p>
Outcomes	<p>Number of participants not cured or improved (subject assessment): A 9/44. B 19/42 Number of participants not cured or improved (investigator assessment): A 9/44. B 17/42</p>

	<p>Number of voids per 24 hours (mean, SD, N): A 9.8 (3.0), 41. B 9.9 (3.8), 43</p> <p>Number of nocturia episodes (mean, SD, N): A 1.7 (1.1), 41. B 1.9 (1.6), 43</p> <p>Number of urgency incontinence episodes per 24 hours (mean, SD, N): A 1.2 (1.6), 41. B 1.8 (2.5), 43</p> <p>Number of moderate to severe urgency episodes per 24 hours (mean, SD, N): A 3.9 (2.8), 41. B 4.5 (3.6), 43</p> <p>Volume voided per 24 hours (cc) (mean, SD, N): A 185.5 (81.1), 41. B 158.7 (99.8), 43</p> <p>Change in number voids per 24 hours (mean, SD, N): A -2.4 (4.0), 41. B -2.5 (3.9), 43</p> <p>Change in number of nocturia episodes per 24 hours (mean, SD, N): A -0.7 (1.0), 41. B -0.6 (1.7), 43</p> <p>Change in number of urgency incontinence episodes per 24 hours (mean, SD, N): A -1.0 (2.2), 41. B -1.7 (3.8), 43</p> <p>Change in number of moderate to severe urgency episodes per 24 hours (mean, SD, N): A -2.2 (4.3), 41. B -2.9 (4.8), 43</p> <p>Change in volume voided per 24 hours (cc) (mean, SD, N): A 32.8 (61.3), 41. B 17.6 (58.4), 43</p>
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Notes

Risk of bias *Risk of bias*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random blocks design stratified by investigational site
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	Withdrawn prior to 12 week follow-up: withdrew consent n = 5; lost to follow-up n = 1; withdrew consent n = 3; treatment unsuccessful n = 3; others n = 1

Methods	<p>Study design: RCT</p> <p>Multicentre or single-centre: multicentre</p> <p>Setting: USA</p> <p>Period: September 2008-January 2009</p> <p>Sample size: "A sample size estimate of approximately 214 participants, 107 per study arm, calculated using a 2-sided Fisher's exact binomial test based on an estimated 60% responder rate in the PTNS group and a 40% responder rate in the sham group with a 5% significance level and 80% power."</p> <p>Follow-up: 13 weeks</p>
Participants	<p>N: 220 randomised (174 women, 46 men), 208 analysed</p> <p>Mean age (no SD): A 62.5; B 60.2</p> <p>Sex: men and women</p> <p>Inclusion criteria: > 18 years of age, score of > 4 on the OAB-Q short form for urgency, average urinary frequency of > 10 voids per day, self-reported bladder symptoms > 3 months, self-reported failed conservative care, discontinued all antimuscarinics for > 2 weeks, capable of giving informed consent, ambulatory and able to use toilet independently without difficulty, capable and willing to follow all study-related procedures</p> <p>Exclusion criteria: pregnant or planning to become pregnant during study duration, neurogenic bladder, Botox® use in bladder or pelvic floor muscles within past year, pacemakers or implantable defibrillators, current UTI, current vaginal infection, use of Interstim®, use of Bion®, Current use of TENS in pelvic region, back or legs, previous PTNS treatment, use of investigational drug/device therapy within past 4 weeks, participation in any clinical investigation involving or impacting gynaecologic, urinary or renal function within past 4 weeks</p>
Interventions	<p>A (n = 110) PTNS. One 30-minute session per week for 12 weeks. 34-gauge needle electrode inserted at a 60° angle approximately 5 cm cephalad to the medial malleolus, slightly posterior to the tibia. PTNS surface electrode placed on the ipsilateral calcaneus and 2 inactive sham surface electrodes, 1 under the little toe and 1 on the top of the foot. Current level of 0.5-9 mA at 20 Hz was selected based on each participant's foot and plantar motor and sensory responses</p> <p>B (n = 110) sham PTNS. One 30-minute session per week for 12 weeks. Streitberger placebo needle was used to simulate the location and sensation of PTNS needle electrode insertion. An inactive PTNS surface electrode was placed on the ipsilateral calcaneus. Two active TENS surface electrodes were placed, 1 under the little toe and 1 on the top of the foot</p>
Outcomes	<p>"responder was defined as reporting bladder symptoms as moderately or markedly improved on a 7-level GRA at week 13"</p> <p>Moderate or marked improvement on global response assessment: A 60/110. B 23/110</p> <p>No improvement in OAB symptoms: A 50/110. B 87/110</p> <p>No improvement in urinary urgency: A 59/103. B 81/105</p> <p>No improvement in urinary frequency: A 54/103. B 82/105</p> <p>No improvement in urgency incontinence: A 64/103. B 81/104</p>

Peters 2010 (Continued)

	<p>Frequency of voiding per 24 hours (mean, SD, N): A 9.8 (2.8), 103. B 11.0 (3.1), 105 Frequency of nocturia (mean, SD, N): A 2.1 (1.4), 103. B 2.6 (1.6), 105 Mean voided vol (cc) (mean, SD, N): A 183.0 (75.6), 103. B 172.6 (90.6), 102 Adverse effects: A 6/110. B 0/110 Change in OAB-Q symptom score (mean, SD, N) (lower score is better): A -36.7 (21.5), 101. B -29.2 (20.0), 102 Change in SF-36 score (mean, SD, N) (higher score is better): A 34.2 (21.3), 103. B 20.6 (20.6), 105</p>
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Notes

Risk of bias *Risk of bias*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"All subjects were randomized 1:1 at the first intervention visit to PTNS or sham using a random block design stratified by investigational site."
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"Subjects and study coordinators were blinded to the intervention"
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	No differential dropout. ITT analysis carried out for primary outcome

Phillips 2012

Methods	<p>Study design: RCT Setting: USA Follow-up: 4 weeks</p>
Participants	<p>N: 74 randomised Sex: men and women Age: not reported Inclusion criteria: symptoms OAB with UUI for at least 6 months, other therapies previously failed, including ≥ anticholinergic drug</p>

Phillips 2012 (Continued)

	Exclusion criteria: not reported
Interventions	A (n = 34 patient-managed neuromodulation system (PMNS) patch - subject placement B (n = 30) patient-managed neuromodulation system (PMNS) patch - investigator placement
Outcomes	% reduction in UUI episodes OAB-Q score Adverse effects
Notes	No useable data. Numbers per group not reported

Risk of bias

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"randomized between two treatment groups"
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not reported

Preyer 2007

Methods	Study design: RCT Multicentre or single-centre: not reported Setting: not reported Period: June 2004 and July 2006 Sample size: not reported Follow-up: 12 weeks
Participants	N: 31 randomised (n analysed unclear) Sex: women Mean (SD) age: 59.4 (10.9) Inclusion criteria: adults with urgency incontinence and urge symptoms Exclusion criteria: contraindications against anticholinergics, pregnancy, tolterodine before

Interventions	A (n = 16) PTNS, one 30-min session per week for 12 weeks B (n =15) tolterodine 2 mg daily for 12 weeks.
Outcomes	Change in number of micturitions per 24 h (mean, 95%CI (SD)*, N): A -0.1 (-3.3 to 3.6 (7.04)), 16. B -0.7 (-2.3 to 3.7 (5.93)), 15. (P = 0.77) Change in number of incontinence episodes per 24 hours (mean, 95%CI (SD)*, N): A -1.3 (0.6 to 3.2 (2.65)), 16. B -2.6 (0.1 to 5.3 (5.14)), 15 Change in number of urgency episodes per 24 hours (mean, 95%CI (SD)*, N): A -9.3 (7.0 to 11.7 (4.80)), 16. B -9.5 (6.3 to 12.7 (6.32)), 15 Side effects: A 1/16. B 6/15 Change in QoL (instrument used not reported) (mean, 95%CI (SD)*, N): A 4.4 (1.7 to 7.1 (5.51)), 16. 4.6 (2.1 to 7.0 (4.84)), 15.
Notes	*SD calculated by FS Dropouts: A 3. B 2. Unclear if these participants included in analysis We contacted the main author of the study to clarify methodological aspects of the study and request further information. Awaiting reply

Risk of bias**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	3 participants (10.3%) in the PTNS group and; 2 (6.9%) in the drug group (tolterodine)

Methods	<p>Study design: RCT</p> <p>Multicentre or single-centre: multicentre</p> <p>Setting: 3 centres in Austria and Germany</p> <p>Period: not reported</p> <p>Details of sample size calculation: “A provisional power calculation based on an exaggerated difference of 20% was performed for this pilot study. A reduction from a mean micturition per 24 h after a 3 months treatment with tolterodine of 13-10.4 under PTNS (assuming a common standard deviation of 2.7) could have been detected with 80% power and a two-sided significance level of 5% with 18 patients per group”</p> <p>Follow up: 3 months’ treatment</p>
Participants	<p>N: 36 randomised and 32 analysed</p> <p>Mean (SD) age: not reported</p> <p>Sex: women</p> <p>Inclusion criteria: female; minimum age of 18 years; complaints of OAB dry or wet consistent with the IUGA/ICS criteria; no prior treatment with PTNS or anticholinergics</p> <p>Exclusion criteria: pregnancy or intention to become pregnant during the study period; active or recurrent UTIs (more than 4 per year); residual urine of more than 100 ml; history of urinary fistula, bladder or kidney stones, interstitial cystitis; history of cystoscopic abnormalities or possible malignancy, diabetes mellitus, cardiac pacemaker or implanted defibrillator; history of anatomic or post traumatic malformations of the lower limbs; immobility; contraindications for anticholinergics or PTNS; disability to understand the study requirements and procedures, advantages and possible side effects</p>
Interventions	<p>A (n = 18 randomized and 16 analysed) PTNS. One 30 min session per week for 3 months. “PTNS was performed as described by Stoller et al. (Stoller 1999) and Vandoninck et al. (Vandoninck 2003) (Urgent PC1 device by UroplastyTM”</p> <p>B (n = 18 randomised and 16 analysed) tolterodine 2 mg twice daily</p>
Outcomes	<p>Micturitions per 24 h (mean, SD, N):</p> <p>A 10.4 (4.1), 16. B 9.1 (3.6), 16</p> <p>QoL measured by VAS (higher score = greater severity) (median, range, N):</p> <p>A 1.9 (0-8), 16. B 2.7 (0-8.5), 16</p> <p>Incontinence episodes in 24 h (median, range, N):</p> <p>A 0 (0-6), 16. B 1 (0-5), 16</p> <p>Adverse effects: A 3/18 (pain at puncture site). B 9/18 (dry mouth and dizziness)</p>
Notes	

Risk of bias**Risk of bias**

Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	<p>“Randomisation was centralised by telephone and the random allocation sequence was generated by computer assistance using a method of adaptive randomisation”</p> <p>“Stratification for randomisation was done for micturitions per 24 h (0-8, 9-12, 13-</p>

Preyer 2015 (Continued)

		24, 25), incontinence episodes in 24 h (0-2, 3-10, 11-18, 19-24, 25), age (18-44, 45-55, 56-65, 66 years), and smoking.”
Allocation concealment (selection bias)	Low risk	“the random allocation sequence was generated by computer assistance using a method of adaptive randomisation”
Blinding of participants and personnel (performance bias) All outcomes	High risk	“The patients and assessors were not blinded”
Blinding of outcome assessment (detection bias) All outcomes	High risk	“The patients and assessors were not blinded”
Incomplete outcome data (attrition bias) All outcomes	Low risk	No differential withdrawal. Adequate reasons for withdrawals (not related to interventions)

Sancaktar 2010

Methods	Study design: RCT Multicentre or single-centre: not reported Setting: Turkey Period: not reported Sample size: not reported Follow-up: 12 weeks
Participants	N: 40 randomised Sex: women Mean age (range): overall 46.4 (33 to 61); mean (SD): A 45.4 (8.7). B 47.4 (10.1) Inclusion criteria: severe OAB symptoms defined as median 6 urgency incontinence episodes per 48 hours Exclusion criteria: stress incontinence, genital prolapse higher than Stage II on POP-Q system, ocular, cardiological, neurological or metabolic disease, history of pelvic surgery ultrasonographic evidence of postvoidal retention more than 100 mL and bladder capacity less than 200 mL, menopausal symptoms indicating significant decrease in QoL, presence of UTI, prior treatment for OAB
Interventions	A (n = 20) tolterodine 4 mg daily for 12 weeks B (n = 20) Stoller Afferent Neuro-stimulation (SANS) plus tolterodine 4 mg daily for 12 weeks. One 30-min session per week for 12 weeks. 34-G acupuncture needle inserted at 30° angle into 2-3 cm superior-medial aspect of tibial medial malleolus along posterior tibial nerve trace. 20 Hz frequency, 0.2 ms duration, amplitude of stimulus adjusted according to participant toleration

Outcomes	<p>Frequency per 24 hours (mean, SD, N): A 6.4 (0.6), 18. B 4.5 (0 [sic]), 20. (P < 0.05)</p> <p>Urgency episodes per 24 hours (mean, SD, N): A 7.6 (0.9), 18. B 5.7 (0.6), 20. (P < 0.05)</p> <p>Incontinence episodes per week (mean, SD, N): A 12.3 (0.8), 18. B 6.4 (0.5), 20. (P < 0.001)</p> <p>IIQ-7 score (mean, SD, N) (higher score is worse incontinence): A 11.2 (2.7), 18. B 9.0 (0.8), 20.</p> <p>Adverse events: Severe dry mouth: A 3/18. B 2/20 Severe constipation: A 2/18. B 2/20 Headache: A 1/18. B. 0/20 Local irritation on puncture site: A N/A. B 1 > 1 adverse event: A 2/18. B 1/20</p>
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Notes	We contacted the main author of the study to clarify methodological aspects of the study and request further information. Awaiting reply
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<i>Risk of bias</i>		<i>Risk of bias</i>
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Randomisation was obtained using a list of random numbers."
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	2 withdrawals from tolterodine alone group; no reason reported

Methods	<p>Study design: RCT Multicentre or single-centre: single-centre Setting: Hospital das Clínicas de Porto Alegre (HCPA), Brazil Period: January 2006-May 2007 Sample size: to detect a difference of one standard deviation in the study variables after 12 weeks of treatment, the sample size was established as 11 participants per group. This sample size assumes a significance level of 5% power of 90% and a correlation between measurements at the 2 different points of 0.5 Follow-up: 12 weeks' treatment, 6 months' follow-up</p>
Participants	<p>N: 32 randomised Sex: Women Age mean (SD): A 54.7 (6.94); B 49.18 (6.06); C 52.09 (13.78) Inclusion criteria: women were older than 30 years of age; SUI or MUI; had not received any clinical or surgical treatment during the previous 6 months; were free of significant genital prolapse (below stage 2 on the pelvic organ prolapse quantification system); and had no urethral sphincter involvement (leak point pressure less than 60 cmH₂O). The criteria for prolapse classification were defined in accordance with International Continence Society (ICS) guidelines Exclusion criteria: not reported</p>
Interventions	<p>All participants received identical specially designed equipment, providing real-time information on the contraction waveform and information or guidance. Vaginal probe transducer for monitoring pelvic muscle contraction pressure during exercises. Programmable for either PFMT plus biofeedback, PFMT plus ES or PFMT without feedback All participants same exercise programme: supine position with rapid contractions (2 seconds contraction, 4 seconds rest) then slow contractions (4 seconds contraction, 4 seconds of rest), repeated 3 times with rest interval A (n = 10) PFMT plus biofeedback for 12 weeks. Device displays information on contraction intensity B (n = 11) PFMT plus ES for 12 weeks. Frequency 50 Hz and pulse duration of 300 μs C (n = 11) PFMT alone for 12 weeks. Participants received no information from device on contraction intensity</p>
Outcomes	<p>Subjective self-evaluation at 12 weeks: Cure or significant improvement: 71.9% (23/32) Partial improvement: 18.8% (6/32) Poor response: 9.4% (3/32) Perineometric intensity (pelvic floor muscle strength) (I_c cm H₂O) (mean, SD, N): 12 weeks: A 57.93 (26.15), 10. B 49.7 (25.87), 11. C 47.67 (25.26), 11 6 months: A 51.12 (28.69), 10. B 41.85 (26.1), 11. C 48.88 (19.25), 11 Number of daytime micturitions (median, IQR, N): 12 weeks: A 7 (4-8.25), 10. B 5 (5-6), 11. C 7 (5-10), 11 6 months: A 7.5 (6-9.25), 10. B 4.5 (4-6), 11. C 1.5 (0-3), 11 Number of nocturia episodes (median, IQR, N): 12 weeks: A 1 (1-2), 10. B 0 (0-1), 11. C 2 (1-2), 11 6 months: A 1.5 (0-3), 10. B 1 (0.75-2.25), 11. C, 1 (0.75-2.25), 11 Number of SUI episodes (median, IQR, N):</p>

Schmidt 2009 (Continued)

	<p>12 weeks: A 1 (0-2), 10. B 0 (0-1), 11. C 2 (0-3), 11 6 months: A 1 (0.75-2.25), 10. B 0.5 (0-1.25), 11. C 0 (0-5.25), 11 Number of UUI episodes (median, IQR, N): 12 weeks: A 0 (0-1.25), 10. B 0 (0-0), 11. C 1 (0-2), 11 6 months: A 0.5 (0-1), 10. B 0 (0-0), 11. C 2 (1-3), 11 KHQ scores (mean, SD, N): 12 weeks: A 44.25 (9.11), 10. B 33.12 (19.54), 11. C 48.7 (22.21), 11 6 months: A 41.12 (15.44), 10. B 28.25 (11), 11. C 49.3 (24.96), 11</p>
Notes	<p>No useable data because SUI and MUI participants not separated. Cure/significant improvement not stratified by treatment group Emailed study author 19/12/2014</p>

<i>Risk of bias</i>		<i>Risk of bias</i>
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Patients were randomly allocated"
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported. Blinding of participants not possible
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"The examiner who performed perineometry was blinded to the patients [sic] group."
Incomplete outcome data (attrition bias) All outcomes	Low risk	All randomised participants included in the analysis. No dropouts reported

Schreiner 2010

Methods	<p>Study design: RCT Multicentre or single-centre: single-centre Setting: Urogynecology Section of the Gynecology Department in São Lucas Hospital of Pontificia Universidade Católica do Rio Grande do Sul, Brazil Period: February 2008-October 2008 Sample size: not reported Follow-up: 12 weeks' treatment, 2 years' follow-up</p>
Participants	<p>N: 52 randomised, 51 analysed Mean (SD) age: overall: 68.3 (5.3); A 67.6 (5.2); B 68.9 (5.4) Sex: women Inclusion criteria: UUI and age of 60 years of more Exclusion criteria: the presence of urinary infection during the recruitment process,</p>

	prior surgery for urinary incontinence, history of genito-urinary cancer, prior pelvic irradiation, pure SUI, genital prolapse above the second degree of Baden Walker, and inability to perform the Kegel exercises
Interventions	All participants: PFMT (Kegel exercises); 15 contractions 3 times per day for 12 weeks A (n = 25) transcutaneous tibial nerve stimulation. One 30-minute session per week for 12 weeks. Pulse duration 200 ms, frequency 10 Hz B (n = 26) PFMT only
Outcomes	Daytime frequency (mean, SD, N): A 5.9 (1.4), 25. B 6.8 (1.9), 26 Change in daytime frequency (mean, SD, N): A -1.4 (2), 25. B -0.2 (0.9), 26 Number of nocturia episodes (mean, SD, N): A 1.3 (1.5), 25. B 2.4 (1.3), 26 Change in nocturia (mean, SD, N): A -1.6 (1.1), 25. B -0.4 (1.1), 26 Number of SUI episodes (mean, SD, N): A 2.4 (3.4), 25. B 4.0 (6.0), 26 Change in SUI episodes (mean, SD, N): A -1.1 (4.9), 25. B -1.9 (3.1), 26 Number of UUI episodes (mean, SD, N): A 1.8 (2.7), 25. B 4.6 (3.7), 26 Change in UUI episodes (mean, SD, N): A -6.3 (5.3), 25. B -1.3 (1.6), 26 Number of participants with > 50% reduction in UUI episodes: A 76.0% (19/25). B 26.9% (7/26) (P = 0.001) Subjective global satisfaction: 12 weeks: A 68.0% (17/25). B 34.6% (9/26) (P = 0.017) 2 years: A 64.7%. B not reported Number of participants with UUI: A 44.0% (11/25). B 80.8% (20/26) ICIQ-SF score (mean, SD, N): A 7.9 (4.5), 25. B 10.6 (4.4), 26 Adverse effects: A 0. B 0
Notes	

Risk of bias**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"The patients were randomly divided (through simple random number generator) into two groups."
Allocation concealment (selection bias)	Unclear risk	Not reported

Schreiner 2010 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	"One patient from group 1 (with electrical stimulation of the tibial nerve) left the study due to health problems unrelated to the therapy"

Schreiner 2014

Methods	Study design: RCT Setting: Brazil Follow-up: 3 months' treatment, 12 months' follow-up
Participants	N: 106 randomised Sex: women Inclusion criteria: elderly women (> 60 years) with UUI Exclusion criteria: not reported
Interventions	A (n = 50) conservative treatment. 12 weeks of bladder retraining and PFME B (n = 51) transcutaneous tibial nerve ES
Outcomes	ICIQ-SF: "there was a greater improvement in the group treated with ES in all parameters." Recurrence of incontinence within 12 months: A not reported. B 16/34 Satisfaction at end of treatment: A 32.0% (16/50). B 66.7% (34/51)
Notes	71% had associated stress incontinence

Risk of bias		Risk of bias
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"the study design was a randomized clinical trial, parallel group"
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not possible to blind participants, other blinding not reported

Schreiner 2014 (Continued)

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	High risk	12-month data reported only for proportion of ES participants satisfied at end of treatment, no 12-month data for bladder training group

Seth 2014

Methods	Study design: RCT Multicentre or single-centre: single-centre Setting: UK Period: not reported Sample size: not reported Follow-up: 12 weeks
Participants	N: 48 randomised and 35 analysed Mean (SD) age: not reported Sex: not reported Inclusion criteria: either multiple sclerosis or idiopathic OAB Exclusion criteria: not reported
Interventions	A (n = 24*) 30 min stimulation once per day for 12 weeks with Geko device B (n = 24*) 30 min stimulation once per week for 12 weeks with Geko device
Outcomes	Improvement in ICIQOAB score: -10.2 (-13.5 to -6.9, P = 0.001) Improvement in ICIQLUTS-QOL score: -40.8 (-57.4 to -24.3, P = 0.000) *Responders: 18/34
Notes	N randomised per group not reported. Outcome data not presented per group Contacted study author for more information 5 February 2014 - replied with data marked *

Risk of bias

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"randomized"
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported

Seth 2014 (Continued)

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	High risk	48 randomised, 35 completed study (differential attrition: 20 with MS, 15 with idiopathic OAB). Unclear how many withdrew from each group. Unclear if all randomised participants were included in analysis

Shepherd 1984

Methods	Study design: RCT Multicentre or single-centre: single-centre Setting: UK Period: not reported Sample size: not reported Follow-up: 12 weeks
Participants	N: 107 randomised, 94 analysed SUI 42 UUI 26 MUI 39 Mean (SD) age: not reported Sex: women Inclusion criteria: SUI, UUI or MUI Exclusion criteria: not reported
Interventions	A (n = 53) ES under general anaesthesia. Single session. Scott electrode in vagina, large indifferent electrode under buttocks. Current up to 40 v, 10-50 Hz for 20 min B (n = 54) sham treatment. Single session. Vaginal electrode but no current
Outcomes	Participants with no improvement in frequency of incontinence: A 16/45. B 18/49 Participants not dry: A 37/45. B 43/49 Participants with no improvement in pad changes: A 27/45. B 31/49 Participants with no improvement in objectively measured pelvic floor control: A 23/45. B 23/49 Participants with no improvement in incontinence: A 18/45. B 16/49
Notes	Not useable because data not presented by SUI/UUI/MUI groups

Risk of bias

Risk of bias

Shepherd 1984 (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Allocated at random into trial and control groups."
Allocation concealment (selection bias)	Low risk	"a sealed envelope was opened stating which group the patient was in"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants blinded. Other blinding not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"Patients' subjective statements were recorded by a single observer who was unaware of the treatment allocation"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No differential dropout. No explanation reported for withdrawals

Shepherd 1985

Methods	Study design: RCT Multicentre or single-centre: not reported Setting: UK Period: not reported Sample size: not reported Follow-up: 6 months
Participants	N: 40 randomised, 15 analysed Mean (SD) age: not reported Sex: women Inclusion criteria: genuine stress incontinence or DO Exclusion criteria: not reported
Interventions	A (n = 6 SUI, 4 DO) ES. Intra-vaginal cushion attached to stimulator worn around the waist. Cushion worn for 8 h per 24, night or day according to participant preference. Stimulation: 50 Hz (SUI participants), 10 Hz (DO participants) B (n = 3 SUI, 2 DO) sham ES. Identical device to Group A but not activated
Outcomes	Subjective and objective improvement in symptoms
Notes	No useable data

Risk of bias

Risk of bias

Bias	Authors' judgement	Support for judgement
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Shepherd 1985 (Continued)

Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Low risk	All participants given identical devices but unaware which were activated. "The code was held by the manufacturer and only broken when the trial was completed."
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Withdrawal per group not reported. Substantial withdrawal overall: 15/40 completed trial

Slovak 2015

Methods	Study design: RCT Multicentre or single-centre: not reported Setting: UK Period: June 2013 and December 2014 Sample size: not reported Follow up: 4 weeks' treatment, then 4 weeks' follow-up
Participants	N: 22 randomised, 19 analysed Mean (SD) age: 59 (7.9) Sex: 9 men, 10 women Inclusion criteria: people with idiopathic OAB symptoms who had not responded or could not tolerate (due to side effects) conventional drug therapy, Exclusion criteria: not reported
Interventions	A (n = 7 analysed) ES with unilateral PTNS with conventional TENS* machine using a pair of adhesive surface electrodes and a stimulus intensity just below that which would cause a motor contraction of toes/shoulder muscles. Electrodes placed above and below the medial malleolus on the right ankle B (n = 6 analysed) ES with bilateral PTNS. Electrodes placed in same position as unilateral stimulation group but on both ankles C (n = 6 analysed) sham stimulation, electrodes placed on the anterior aspect of the left shoulder
Outcomes	Decrease in micturitions per 24 h (mean, 95%CI, N): A 1.7 (-9 to 3.7), 7. B 2.8 (-6.7 to 1.1), 6. C 0.7 (-2.1 to 6.3) Decrease in urgency episodes (mean, 95%CI, N): A 1.3 (-5.0 to 2.2), 7. B 3.2 (-8.5 to 2.1), 6. C 0.7 (-5.0 to 3.7) Number of responders (defined as > 30% reduction in daily micturitions and/or urgency

Slovak 2015 (Continued)

	episodes, and self-reported subjective improvement: A 3/7. B 2/6. C 1/6
Notes	*no explanation given for TENS abbreviation “Initial effects were reported after the first week of the therapy in all responders. In the majority of responders the effects ceased at the follow-up visit, four weeks after therapy had finished.”

<i>Risk of bias</i>		<i>Risk of bias</i>
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	“computer-generated”
Allocation concealment (selection bias)	Low risk	“opaque sealed envelopes”
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants blinded. “The participants were unaware that one of the stimulation groups was considered as a placebo group.” “The researcher who provided the training to participants was not blinded...data were recorded only by the participants”
Blinding of outcome assessment (detection bias) All outcomes	Low risk	“the research team did not interact with participant's outcome questionnaires and bladder diary, and data were recorded only by the participants”
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Per-protocol analysis. No reasons given for participant withdrawal

Smith 1996

Methods	Study design: RCT Multicentre or single-centre: single-centre Setting: Department of Urology, Lahey Clinic, Burlington, Massachusetts, USA Period: October 1992- January 1994 Sample size: not reported Follow-up: 16 weeks
Participants	N: 57 randomised in total. 38 with DI randomised and analysed Mean age (range): A 65 (45-82) B 60 (44-73) Sex: Women Inclusion criteria: genuine SUI or DI Exclusion criteria: type 3 SUI, pregnancy, history of prolonged urinary retention, vaginal

Smith 1996 (Continued)

	vault prolapse, diminished sensory perception or cardiac pacemaker
Interventions	A (n = 20) propantheline bromide 7.5 mg to 45 mg 2-3 times daily (“or until side effects prevented its continuance”) for at least 4 months B (n = 18) ES. 5-s impulse time, duty cycle 1-2, increasing monthly treatment time from 15, 30, 45 and 60 min. Amplitude started at 5 mA and did not exceed 25 mA. Twice daily for 4 months
Outcomes	Number of participants cured (defined as cessation of incontinence and no longer requiring pads): A 3/20. B 4/18 Number of participants with objective improvement (defined as reduction of $\geq 50\%$ in episodes and pads, and ≤ 10 voiding episodes per 24 hours): A 7/20. B 9/18 Number of participants with no improvement: A 10/20. B 5/18
Notes	

<i>Risk of bias</i>		<i>Risk of bias</i>
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	“patients were randomized to 1 of 2 treatment arms”
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not possible to blind participants. Blinding of others not reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not reported

Soomro 2001

Methods	<p>Study design: cross-over RCT</p> <p>Multicentre or single-centre: single-centre</p> <p>Setting: University of New South Wales, New South Wales, Australia</p> <p>Period: not reported</p> <p>Sample size: the study was designed to obtain a type 1 error of 5% and a power of 85% which gave a sample size of 35</p> <p>Follow-up: 6 weeks</p>
Participants	<p>N: 43 randomised and analysed</p> <p>Mean (SD) age: 50 (15)</p> <p>Sex: 13 men, 30 women</p> <p>Inclusion criteria: history of frequency, urgency and urge incontinence with no previous treatment for at least 6 months</p> <p>Exclusion criteria: not reported</p>
Interventions	<p>A (n = 43) oxybutynin 2.5 mg twice daily, titrated to 5 mg 3 times daily by day 7</p> <p>B (n = 43) TENS 20 Hz, pulse width 0.2 ms on a continuous mode up to 6 hours daily for 6 weeks</p> <p>All participants had washout period of 2 weeks then 6 weeks of the other treatment</p>
Outcomes	<p>Number of daily voids (mean, SD, N): A 9 (5), 43. B 9 (4), 43</p> <p>Number of participants with no subjective improvement: A 30/40. B 29/38</p> <p>Total bladder capacity (mL) (mean, SD, N): A 303.3 (142.5), 43. B 222.1 (99.2), 43</p> <p>Volume at first desire to void (mL) (mean, SD, N): A 191.8 (130.1), 43. B 117.4 (84.7), 43</p> <p>Residual volume (mL) (mean, SD, N): A 81.3 (81.3), 43. B 38.9 (55.03), 43</p> <p>Volume at instability (mL) (mean, SD, N): A 180.9 (92.8), 43. B 96.3 (55.9), 43</p> <p>Number of participants with > 25% improvement in bladder capacity: A 6/43. B 2/43</p> <p>Number of participants with > 25% improvement in daily voids: A 21/43. B 24/43</p> <p>Number of participants with side effects (N unclear):</p> <p>Dry mouth: A 87.2% (37/43). B 6.2% (3/43)</p> <p>Blurred vision: A 52.6% (23/43). B 6.2% (3/43)</p> <p>Dry skin: A 29.7% (13/43). B 6.2% (3/43)</p> <p>Skin irritation: A 25.6% (11/43). B 28.1% (12/43)</p> <p>Cost per participant: A oxybutynin £15.00 for 6 weeks B ES, including consumables, £60 for 6 weeks</p>
Notes	<p>N assumed to be 43 unless otherwise stated</p> <p>Data not useable. Cross-over design requires paired difference and SD for each outcome but paper reports insufficient data for analysis</p> <p>Contacted study author asking for further data 26 January 2015</p>

<i>Risk of bias</i>		<i>Risk of bias</i>
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Patients were randomized to initial treatment with either transcutaneous electrical nerve stimulation or oxybutynin. After a washout period of 2 weeks, patients were started on the second arm of treatment"
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not possible to blind participants. Blinding of others not reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Unclear if data available for all participants. Also risk of carry-over effect is unclear

Sotelo 2011

Methods	Study design: RCT Multicentre or single-centre: single-centre Setting: USA Period: not reported Sample size: not reported Follow-up: 8 days
Participants	N: 50 randomised and analysed Mean (SD) age: 57 Sex: not reported Inclusion criteria: OAB Exclusion criteria: not reported
Interventions	A (n = 15) ES, no tub bathing or exercise. Horizontal placement of electrode patch near sacral nerve B (n = 15) ES, no tub bathing or exercise. 30° angle placement of electrode patch near sacral nerve C (n = 5) ES, with daily tub bathing or swimming. Horizontal placement of electrode patch near sacral nerve D (n = 5) ES, with daily tub bathing or swimming. 30° angle placement of electrode patch near sacral nerve E (n = 5) ES, with daily 30-min exercise regimen. Horizontal placement of electrode patch near sacral nerve

Sotelo 2011 (Continued)

	F (n = 5) ES, with daily 30-min exercise regimen. 30-degree angle placement of electrode patch near sacral nerve
Outcomes	Adverse effects: 1 participant (not reported by group) Patch awareness, discomfort, bother, 1-10 VAS (mean, SD), N): A + B: 1.4 (1.1), 30. C + D: 1.2 (0.9), 10. E + F: 1.3 (1.0), 10
Notes	No useable data

Risk of bias		Risk of bias
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"randomized to one of two sacral placement angles"
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not possible
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Data not reported per group

Souto 2014

Methods	Study design: RCT Multicentre or single-centre: not reported Setting: Brazil Period: August 2008-May 2010 Details of sample size calculation: "a prior power calculation...even after dropout, 80% sample power was kept (post hoc analysis)" Follow-up: 12 weeks' treatment, 6 months' follow-up
Participants	N: 75 randomised, 58 analysed Mean (range) age: A 56.9 (33-77). B 57.7 (34-79). C 60.1 (33-77) Sex: women Inclusion criteria: clinical complaints of OAB: urinary frequency, nocturia, and/or urgency incontinence with negative urinalysis and urine culture Exclusion criteria: previous treatment, residual urine, cognitive and psychiatric deficits, pregnancy, glaucoma, SUI, any pelvic organ prolapse quantification system (POPQ) C grade II, neurogenic OAB, those using anticholinergic drugs, calcium antagonists, b-antagonists, and dopamine antagonists

Interventions	A (n = 25) ES of posterior tibial nerve using Neurodyn Portable. 10 Hz frequency, pulse width of 250 µs. Two 30-minute sessions per week for 12 weeks B (n = 25) slow release oxybutynin 10 mg, once daily for 12 weeks C (n = 25) multimodal treatment, A + B
Outcomes	Frequency (mean*, N): 12 weeks: A 8, 18. B 7.9, 19. C 7.6, 21. (P = 0.75) 24 weeks: A 7.9, 18. B 9.2, 19. C 7.8, 21 (P = 0.51) Participants with urinary incontinence: 12 weeks: A 11% (2/18). B 31% (6/19). C 19% (4/21) 24 weeks: A 14% (3/18). B 34% (6/19). C 18% (4/21) Participants with nocturia: 12 weeks: A 11% (2/18). B 5% (1/19). C 14% (3/21). (P = 0.24) 24 weeks: A 13% (2/18). B 15% (3/19). C 14% (3/21). (P = 0.51) International Consultation on Incontinence Questionnaire (ICIQ-SF) score (mean*, range, N): 12 weeks: A 7.2 (0-18), 18. B 9.8 (0-18), 19. C 7.9 (0-14), 21 24 weeks: A 8.3 (0-20), 18. B 13.3 (8-20), 19. C 7.4 (0-14), 21 ICIQ-OAB (mean*, range, N): 12 weeks: A 5.9 (1-11), 18. B 4.6 (0-10), 19. C 2.9 (0-5), 21 24 weeks: A 6.1 (1.-12), 18. B 9.2 (4-13), 19. C 3.0 (0-5), 21 Bother: 0-10 analogue scale (mean, range, N): 12 weeks: A 3.9 (0-8), 18. B 3.4 (0-9), 19. C 1.7 (0-4), 21 24 weeks: A 4.2 (0-8), 18. B 7.0 (2-10), 19. C 1.6 (0-4), 21
Notes	*SD not reported

<i>Risk of bias</i>		<i>Risk of bias</i>
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"patients were divided randomly into three groups using online randomization"
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not possible to blind participants. Personnel not reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	"Patients who failed to comply with the 12 weeks of treatment (Week 12) and/or did not attend the reassessment after treatment (Week 24) at 6 months follow-up were ex-

Souto 2014 (Continued)

		cluded from analysis.” No differential withdrawal. No reasons given for withdrawals
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Spruijt 2003

Methods	Study design: RCT Multicentre or single-centre: single-centre. Setting: Vrije University Medical Center Amsterdam, the Netherlands Period: January 1996 and May 1998 Sample size: 75 participants for this study (alpha = 5%, beta 10%, estimated difference = 10%) Follow-up: 8 weeks
Participants	N: 72 enrolled, 37 randomised, 35 analysed Sex: women Median age (range): A 72 (65-92); B 74 (66-86) Inclusion criteria: women ≥ 65 with symptoms of SUI, UUI or MUI for ≥ 3 months, urinary leakage of 10 cc or more per 24 h Exclusion criteria: persistent UTI (positive urine culture after antibiotic treatment), recurrent UTI (within 4 weeks after treatment), bladder pathology or dysfunction because of fistula, tumour, pelvic irradiation, neurological or other chronic conditions (diabetes mellitus, Parkinson's disease), any incontinence treatment during the past 6 months, genital prolapse to, or beyond, the introitus, having a pacemaker, and insufficient mental condition/cognition
Interventions	A (n = 25) ES. Three 30-min sessions, with 5 min rest between each 15 min of treatment, per week for 8 weeks. Frequency 50 Hz for predominant SUI and 20 Hz for predominant UUI. 2-s contraction time and duty cycle of 1-2 s, stimulation intensity gradually increasing up to the level of tolerable discomfort (0-100 mA) B (n = 12) PFMT. Verbal instructions on performing Kegel exercises at home for 8 weeks
Outcomes	Urinary leakage per day (mg) (mean, range, N): A 65 (0-489), 24. B 26 (4-157), 11 Number of participants with no objective improvement: A 17/24. B 7/11 Pelvic muscle strength (mean, range, N): A 15.375 (1.75-40.00), 24. B 10.00 (3.25-23.00) Number of participants with DI defined as spontaneous detrusor contraction(s) of 15 cm H ₂ O or more on (ambulant) urodynamic registration (ICS standard): A 14/24. B 5/11 Number of participants with no subjective improvement (measured with PRAFAB score) : A 13/24. B 6/11
Notes	No useable data - not presented by SUI/UUI/MUI participants Study authors contacted for data 09-02-2015

Spruijt 2003 (Continued)

<i>Risk of bias</i>		<i>Risk of bias</i>
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Blocked randomisation according to Pocock's method
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	There was one participant in each group lost to follow-up.

Svihra 2002

Methods	Study design: quasi-RCT Multicentre or single-centre: not reported Setting: Slovakia Period: 2001 Sample size: not reported Follow-up: 5 weeks
Participants	N: 28 Sex: women Mean age (range): 54 (45-63) Inclusion criteria: OAB without bladder outlet obstruction confirmed by urodynamic examination Exclusion criteria: not reported
Interventions	A (n = 9) SANS ES (Stoller Afferent Neuro Stimulation). One 30-min session per week for 5 weeks. Frequency 1 Hz, square impulse duration 0.1 ms, intensity 25 mA B (n = 10) oxybutynin 3 mg 3 times per day C (n = 9) no active treatment
Outcomes	IPSS (mean, SD, N) A 6 (4), 9. B not reported. C not reported Incontinence Quality of Life Questionnaire (I-QoL) score (mean, SD, N): A 68 (20), 9. B not reported. C not reported Behavioural Urge Score (BUS) (mean, SD, N): A 0.43 (0.16), 9. B not reported. C not reported Change in IPSS (mean, N):

Svihra 2002 (Continued)

	<p>A 60%, 9. B 80%, 10. C 20%, 9 Change in I-QoL (mean, N): A 100%, 9. B 90%, 10. C 25%, 9 Change in BUS (mean, N): A 30%, 9. B 30%, 10. C 5%, 9 Number of participants with no significant improvement in IPSS, IQoL, BUS: A 4/9. B not reported. C 9/9 Number of participants with adverse effects: A 0/9. B 2/10 (dry mouth). C not reported</p>
Notes	<p>Only adverse events data were useable We contacted the main author of the study to clarify methodological aspects of the study and request further information. Awaiting reply</p>

<i>Risk of bias</i>		<i>Risk of bias</i>
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	"Nine randomly chosen females formed the group with SANS stimulation, ten females formed the oxybutynin group and nine females the group without treatment."
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not reported

Vahtera 1997

Methods	<p>Study design: RCT Multicentre or single-centre: single-centre Setting: Finland Period: not reported Details of sample size calculation: not reported Follow-up: 2 weeks' treatment then 6 months' follow-up</p>
Participants	<p>N: 80 randomised, unclear how many analysed Mean (SD) age: A women 42.2 (8.9). A men 45.3 (6.3). B women 45.7 (10.7). B men 41.8 (11.8)</p>

Vahtera 1997 (Continued)

	<p>Sex: 50 women, 30 men</p> <p>Inclusion criteria: stable phase of MS, baseline Expanded Disability Score \leq 6.5, LUTS, postvoid residual volume < 100 mL</p> <p>Exclusion criteria: pregnancy, cardiac pacemaker or any metallic implant near the treated area, history of pelvic malignancy, dementia or any nervous system disorder other than MS</p>
Interventions	<p>A (n = 40) ES. 6 sessions over two weeks. Intravaginal electrodes for women, intra-anal for men. 10 minutes of each frequency: 5-10 Hz, 10-50 Hz, 50 Hz (7 s pulse, 25 s pause), with 3 min rest in between. Currents at maximal tolerated intensity. After 6 ES sessions biofeedback used to teach PFME, participants advised to continue PFME 3-5 times per week for \leq 6 months</p> <p>B (n = 40) no active treatment</p>
Outcomes	<p>Urgency, urine leakage, volume of urine loss, voiding need during daytime, slow urine flow, sensation of incomplete bladder emptying, need of assistance in emptying bladder</p>
Notes	<p>No useable data: no outcomes reported by treatment group</p>

Risk of bias

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Men and women were separately randomized into a treatment group"
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not possible
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No outcomes reported for control group

Methods	<p>Study design: cross-over RCT</p> <p>Multicentre or single-centre: not reported</p> <p>Setting: Italy</p> <p>Period: June 2010-October 2011</p> <p>Sample size: not reported</p> <p>Follow-up: approximately 6 months (40 days' drug treatment, 6 weeks ES, with 3-month washout period in between)</p>
Participants	<p>N: 40 randomised, 30 analysed</p> <p>Sex: women</p> <p>Mean age (range): 62 (35-81)</p> <p>Inclusion criteria: women with OAB syndrome</p> <p>Exclusion criteria: stress incontinence, UTI, neurological disease, bladder lithiasis, genital prolapse higher than stage II on POP-Q system, uncontrolled narrow angle glaucoma, pelvic tumours, postvoid residual urine \geq 100 mL, or previously treated with pelvic surgery, radiation therapy or antimuscarinic agents</p>
Interventions	<p>A (n = 20) solifenacin succinate, 5 mg daily for 40 days. 3-month washout period then percutaneous tibial nerve stimulation, 30-min session twice a week for 6 weeks</p> <p>B (n = 20) reverse of group A</p>
Outcomes	<p>Number of voids per 24 hours (mean, SD, N):</p> <p>Post-SS: A 10 (2.1), 14. B 10.4 (1.8), 16</p> <p>Post-ES: A 8.5 (2.3), 14. B 9.4 (1.9), 16</p> <p>Number of nocturia episodes:</p> <p>Post-SS: A 1.9 (1.4), 14. B 2.1 (1.4), 16</p> <p>Post-ES: A 1.6 (1.3), 14. B 1.7 (0.9), 16</p> <p>Number of urgency incontinence episodes:</p> <p>Post-SS: A 2.6 (1.6), 14. B 2.7 (1.6), 16</p> <p>Post-ES: A 1.7 (1.3), 14. B 1.7 (1.5), 16</p> <p>Voided volume (cc?) (mean, SD, N):</p> <p>Post-SS: A 147.4 (27.5), 14. B 145.5 (29.6), 16</p> <p>Post-ES: A 157.5 (25.5), 14. B 156.1 (18.4), 16</p> <p>QoL measured with Overactive Bladder Questionnaire Short Form (6 item OAB-Q SF score (mean, (SD), N)) (lower score is better):</p> <p>Post-SS: A 3.2 (1.1), 14. B 3.5 (1.2), 16</p> <p>Post-ES: A 2.7 (1.0), 14. B 3.0 (1.0), 16</p> <p>QoL measured with Overactive Bladder Questionnaire Short Form (13 item OAB-Q SF score (mean, (SD), N)) (lower score is better):</p> <p>Post-SS: A 3.1 (1.1), 14. B 3.4 (1.2), 16</p> <p>Post-ES: A 2.9 (0.9), 14. B 2.9 (1.1), 16</p> <p>Urgency measured with Patient Perception of Intensity of Urgency Scale (PPIUS score (mean, (SD), N)) (lower score is better):</p> <p>Post-SS: A 2.7 (1.2), 14. B 2.7 (1.3), 16</p> <p>Post-ES: A 2.1 (0.9), 14. B 2.2 (1.1), 16</p> <p>Improvement measured with Patient Global Impression of Improvement questionnaire (PGI-I score [mean, SD, N]) (lower score is more improvement)</p> <p>Post-SS: A 2.9 (1.1), 14. B 3.1 (1), 16</p> <p>Post-ES: A 2.1 (0.7), 14. B 2.3 (0.7), 16</p>

Vecchioli-Scaldazza 2013 (Continued)

Notes	We included data from first period of randomisation only	
Risk of bias		Risk of bias
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Follow-up was performed by a physician who was not involved in the study
Incomplete outcome data (attrition bias) All outcomes	Low risk	A: 2 participants withdrew due to side effects, 2 withdrew after SS due to improved symptoms, 2 refused to undergo further therapy B: 3 withdrew due to improved symptoms, 1 refused to undergo further therapy

Vohra 2002

Methods	Study design: RCT Multicentre or single-centre: single-centre Setting: Bedford, UK Period: not reported Sample size: not reported Follow-up: 12 weeks
Participants	N: 22 randomised, 21 analysed Sex: not reported Mean age (range): 52.6 (28-78) Inclusion criteria: symptoms of at least six months duration, clinical diagnosis of urgency, frequency syndrome and urodynamic findings of DO Exclusion criteria: not reported
Interventions	A (n = 11) Stoller Afferent Nerve Stimulation (SANS) one 30-min session per week for 12 weeks. Stimulation of posterior tibial nerve with percutaneous needle, current up to 10 mA B (n = 10) sham treatment without nerve stimulation

Vohra 2002 (Continued)

Outcomes	Number of participants with no improvement: A 2/11. B 10/10
Notes	---

Risk of bias *Risk of bias*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Patients were computer randomised to either the treatment arm or as controls"
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	Only one participant discontinued the treatment.

Walsh 2001

Methods	Study design: RCT Multicentre or single-centre: not reported Setting: not reported Period: not reported Sample size: not reported Follow-up: not reported
Participants	N: 146 randomised and analysed Mean age (range): 47 (17-79) Sex: 35 men /111 women Inclusion criteria: urgency incontinence; idiopathic DI, SU, or DH secondary to either spinal injury, myelomeningocele, or multiple sclerosis Exclusion criteria: not reported
Interventions	A (n = 74) transcutaneous neurostimulation. One session: electrode pads of a transcutaneous neurostimulator (Coba 208 neurostimulator unit, Tenscare Ltd., Surrey, UK) were affixed bilaterally to the skin overlying the S3 dermatomes (situated at the junction of buttock and upper thigh) in all participants. Standard urodynamic filling cystometry was performed via a dual-lumen 7-Ch fluid filled catheter system at a 50 mL/minute fill rate B (n = 72) sham treatment. Standard urodynamic filling cystometry was performed via a

	dual-lumen 7-Ch fluid filled catheter system at a 50 mL/minute fill rate. Electrode pads in place but without applying current
Outcomes	<p>Infused bladder volume (mL) at FDV (mean, SD, N): A 167.2 (11.3), 74. B 114.2 (10.7), 72</p> <p>Detrusor pressure at FDV (mean, SD, N): A 8.4 (1.3), 74. B 9.4 (1.5), 72</p> <p>Infused bladder volume (mL) at SDV (mean, SD, N): A 247.4 (12.8), 74. B 193.7 (18.4), 72</p> <p>Detrusor pressure at SDV (mean, SD, N): A 10.9 (3.1), 74. B 10.6 (1.8), 72</p> <p>Infused bladder volume (mL) at sensation of urgency (Urge) (mean, SD, N): A 331.5 (15.9), 74. B 255.4 (11.4), 72</p> <p>Detrusor pressure at Urge (mean, SD, N): A 18.6 (3.2), 74. B 22.6 (5.3), 72</p> <p>Maximum infused cystometric capacity (mL) (CMax) (mean, SD, N): A 404.2 (26.7), 74. B 315.9 (22.9), 72</p> <p>Detrusor pressure at CMax (mean, SD, N): A 20.5 (3.2), 74. B 25.9 (3.5), 72</p>
Notes	We contacted the main author of the study to clarify methodological aspects of the study and request further information. Awaiting reply

Risk of bias**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Patients were randomized into age- and gender-matched control and study groups."
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	All participants completed the study and were included in the analysis

Methods	<p>Study design: RCT</p> <p>Multicentre or single-centre: not reported</p> <p>Setting: Taiwan</p> <p>Period: July 2001-December 2002</p> <p>Sample size: on the basis of the outcome measures (including QOL assessment, bladder diary, participant perception of improvement and satisfaction with treatment, and the improvement rate of ES, PFMT, and BAPFMT, which was 49%, 82.39%, and 80.7%, respectively), the authors conducted a test with a significance level of 0.05 and power of 0.9 and anticipated that groups of equal size were required. The total sample size required was at least 109.5</p> <p>Follow-up: 12 weeks</p>
Participants	<p>N: 120 randomised, 103 analysed</p> <p>Mean age: A 50.09; B 52.32; C 55.74</p> <p>Sex: women</p> <p>Inclusion criteria: OAB symptoms for ≥ 6 months, 16-75 years old, frequency of voiding ≥ 8 times per day, ≥ 1 urgency incontinence episode per day</p> <p>Exclusion criteria: pregnancy, deafness, neurologic disorders, diabetes mellitus, pacemaker or intrauterine device use, genital prolapse greater than Stage II of the International Continence Society grading system, residual urine greater than 100 mL, and UTI</p>
Interventions	<p>A (n = 40) PFMT. At least 3 times daily, performed according to PERFECT scheme (power/endurance/repetition//fast contraction),</p> <p>B (n = 38) BAPFMT. Intravaginal electromyogram probe (Periform, Neen Health-Care) twice per week, participants contracted or relaxed pelvic floor muscles according to visual EMG signals. Also encouraged to perform PFMT at home according to PERFECT scheme</p> <p>C (n = 42) ES. Two 20-min sessions per week with intravaginal electrode (Periform, Neen HealthCare); biphasic, symmetric, pulsed current with frequency of 10 Hz, pulse width 400 μs, duty cycle of 10 s on, 5 s off, and intensity varying with patient tolerance (minimum 20-63 mA, maximum 40-72 mA)</p>
Outcomes	<p>Number of participants with urgency incontinence (no improvement): A 21/34. B 17/34. C 17/35</p> <p>Number of participants with no improvement in OAB: A 21/34. B 17/34. C 17/35</p> <p>KHQ total score (mean, SD, N) (lower score is better): A 50.27 (171.42), 34. B 185.86 (176.57), 34. C 180.08 (176.03), 35</p> <p>Data for all 9 KHQ domains available: see Table II</p>
Notes	<p>Gives data for incontinence episodes per day but then states “We decided not to use this parameter as an outcome measure because of the large number of incomplete records, which could have resulted in a statistical bias.”</p> <p>We contacted the main author of the study to clarify methodological aspects of the study and request further information. Awaiting reply</p>

*Risk of bias**Risk of bias*

Bias	Authors' judgement	Support for judgement
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Wang 2004 (Continued)

Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Low risk	“The allocation of the three study groups was undertaken by sequentially opening a sealed envelope, prepared by the Biostatistics Center for Chang Gung Medical College in blocks of 6”
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants could not be blinded. “The physiotherapist conducted the regimens while unaware of the progress and outcomes of the interventions.”
Blinding of outcome assessment (detection bias) All outcomes	Low risk	“The principal investigator was not involved in any of the interventions and was unaware of the group allocation.”
Incomplete outcome data (attrition bias) All outcomes	Low risk	No differential dropout. Adequate explanation for dropouts

Wang 2006

Methods	<p>Study design: RCT</p> <p>Multicentre or single-centre: single-centre</p> <p>Setting: Taiwan</p> <p>Period: July 2004-November 2005</p> <p>Sample size: on the basis of the reduction rate of urge incontinence after ES, oxybutynin, and placebo (51%, 7; 76%, 5; and 19%, 8 respectively), we conducted a test with a significance level of 0.05 and power of 0.95 and anticipated that groups of equal size were required. We concluded that at least 72 women were required</p> <p>Follow-up: 12 weeks</p>
Participants	<p>N: 74 randomised, 68 analysed</p> <p>Sex: women</p> <p>Mean age (SD): not reported</p> <p>Inclusion criteria: OAB \geq 6 months, age 16-80, in particular urinary urgency 4 times or more per day</p> <p>Exclusion criteria: pregnancy, neurologic disorders, diabetes mellitus, demand cardiac pacemaker or intrauterine device use, genital prolapse greater than Stage II of the International Continence Society grading system, a postvoid residual urine volume greater than 100 mL, overt SUI, a history of anti-incontinence surgery, and UTI</p>
Interventions	<p>A (n = 25) ES. Two 20-min sessions per week. Biphasic, symmetric, pulsed current with a frequency of 10 Hz, pulse width of 400 ms, duty cycle of 10 s on and 5 s off, and intensity varying with participant tolerance (minimum 20-63 mA and maximum 40-72 mA)</p> <p>B (n = 26) oxybutynin 2.5 mg, 3 times per day for 12 weeks</p>

	C (n = 23) placebo tablets identical to oxybutynin, 3 times per day for 12 weeks
Outcomes	<p>No improvement in urgency: A 10/24. B 14/23. C 19/21</p> <p>Daily voided volume (mL) (median, range, N): A 2270 (1210-3106), 24. B 2100 (1619-3200), 23. C 2305 (1351-3221) 21</p> <p>Pad count (median, range, N): A 0 (0-2), 24. B 0 (0-2.5), 23. C 1 (0-3), 21</p> <p>Urgency episodes per 24 h (median, range, N): A 1.0 (0.0-12.3), 24. B 6 (0.5-13), 23. C 7.4 (3.9-13.4), 21</p> <p>Frequency per 24 h (median, range, N): 7.8 (1.8-13.0), 24. B 7.4 (2-14), 23. C 10 (6.6-16.3), 21</p> <p>Nocturia episodes per night (median, range, N): A 0 (0-3.0), 24. B 0 (0-2.0), 23. C 1 (0-3.6), 21</p> <p>Urgency incontinence episodes per 24 h (median, range, N): A 0.5 (0-2), 24. B 0 (0-2), 23. C 1 (0-2), 21</p> <p>Change in daily voided volume (mL) (median, range, N): A 70 (-216 to 1190), 24. B 10.5 (-1031 to 962), 23. C -14.5 (-590 to 413), 21</p> <p>Change in pad count (median, range, N): A -0.9 (-2.1 to 2), 24. B 0 (-1 to 2), 23. C 0 (-4 to 3), 21</p> <p>Change in urgency episodes per 24 h (median, range, N): A -3 (-14 to 0.5), 24. B -3 (-12 to -0.1), 23. C -1.3 (-10.5 to 2)</p> <p>Change in frequency per 24 h (median, range, N): A -3.0 (-14 to 0.5), 24. B -2.15 (-12.8 to 2.3), 23. C -0.75 (-6.5 to 2.3)</p> <p>Change in nocturia episodes per night (median, range, N): A -0.8 (-6.5 to 0.4), 24. B 0 (-2 to 1), 23. C 0 (-1.5 to 2)</p> <p>Change in urgency incontinence episodes per 24 h (median, range, N): A 0 (-2 to 2), 24 B 0 (-1 to 1), 23. C 0 (-2 to 1), 21</p>
Notes	Contacted study author December 2014 to clarify if this is different study from Wang 2009. Awaiting reply

*Risk of bias**Risk of bias*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Low risk	"The allocation of the three study groups was undertaken by sequentially opening a sealed envelope, prepared by the Biostatistics Center for Chang Gung Medical College in blocks of six for each patient"
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"For the pharmacotherapy groups, the patients and all investigators were unaware of the regimen they received from the central pharmacy of our hospital."

Wang 2006 (Continued)

		Not possible to blind ES group
Blinding of outcome assessment (detection bias) All outcomes	Low risk	“The principal investigator was not involved in any of the interventions and was unaware of the group allocation.” “For the pharmacotherapy groups, the patients and all investigators were unaware of the regimen they received from the central pharmacy of our hospital.”
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	“One woman in the ES group withdrew because of fear of the electricity. Three women in the oxybutynin group withdrew, all because of intolerable dry mouth. Two women in the placebo group withdrew because they felt no response.”

Wang 2009

Methods	Study design: RCT Multicentre or single-centre: single-centre Setting: Taiwan Period: July 2006-November 2007 Sample size: calculations for the treatment and placebo groups were based on the assumption that participants in the treatment groups had a 0.76 probability and others in the placebo group had a 0.36 probability of achieving a better outcome (increased UFI). To achieve 0.80 power with 0.05 significance level, it required at least 24 participants in each group Follow-up: 12 weeks
Participants	N: 73 randomised, 73 analysed Sex: women Mean age (SD): overall 53.14 (9.98); A 51.46 (9.92); B 54.92 (9.83); C 53.17 (10.30) Inclusion criteria: OAB for ≥ 6 months (symptom of urgency ≥ 3 times daily) Exclusion criteria: pregnancy, neurologic disorders, diabetes mellitus, demand cardiac pacemaker or intrauterine device use, genital prolapse greater than the ICS grading system stage II, overt SUI, a history of anti-incontinence surgery, UTI and participants receiving any OAB treatment during the 14-day washout/run-in period preceding randomisation
Interventions	A (n = 26) ES. Two 20-min sessions per week for 12 weeks with intravaginal electrode (Periform, Neen HealthCare). Biphasic, symmetric, pulsed current with varying intensity B (n = 24) Oxybutynin. Three 2.5 mg per day for 12 weeks C (n = 23) placebo. 1 tablet identical to oxybutynin, 3 times per day for 12 weeks
Outcomes	No improvement in urgency: A 9/26. B 12/24. C 20/23 Number of micturitions per 24 hours (median, range, N): A 7.05 (2.7, 12), 26. B 5.35 (1, 13.1), 24. C 8.8 (4.1, 13), 23

	<p>Number of incontinence episodes (median, range, N): A 0.85 (0, 2.8), 26. B 0.3 (0, 2.1), 24. C 0.8 (0, 4.3), 23</p> <p>Number of urgency episodes (median, range, N): A 2.4 (0, 6.9), 26. B 3.05 (1, 8.1), 24. C 7.2 (3.5, 10.2), 23</p> <p>Number of nocturia episodes per night (median, range, N): A 1.65 (0, 4.3), 26. B 1.45 (0, 5.4), 24. C 3 (0.1, 4.1), 23</p> <p>Change in number of micturitions per 24 hours (median, range, N): A 3.6 (-2.1, 7.2), 26. B 5.3 (-3.5, 10.9), 24. C 1.6 (-5.2, 7.7), 23</p> <p>Change in number of incontinence episodes (median, range, N): A 0 (-2.8, 3.3), 26. B 0.4 (-0.3, 3.2), 24. C 0.2 (-2.5, 2.2), 23</p> <p>Change in number of nocturia episodes per night (median, range, N): A 2.8 (-2.7, 7.8), 26. B. 2.35 (-3.1, 6.2), 24. C -0.3 (-6.2, 4.7), 23</p> <p>Change in number of nocturia episodes per night (median, range, N): A 0 (-3.2, 3.5), 26. B 0.45 (-5.4, 3), 24. C 0 (-4.1, 2.7), 23</p> <p>KHQtotal score (median, range, N): A 142.25 (-11.5, 432.4), 26. B 104.75 (-49.9, 383.8), 24. C 36.7 (-137.2, 525), 23</p> <p>All nine KHQ domains available: see Table 5</p>
Notes	Contacted author to clarify if this study is study is separate from Wang 2006. Awaiting reply

Risk of bias**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Predetermined computer-generated randomization code" was used. Participants were 'assigned randomly in sequential order."
Allocation concealment (selection bias)	Unclear risk	Not reported.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"The principal investigator was not involved in any of the interventions and was unaware of the group allocation." "For the pharmacotherapy groups, [groups B and C] the subjects and all investigators were unaware of the regimen they received from the central pharmacy of our hospital." Group C received "a placebo looking exactly the same as Oxybutynin."
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.

Wang 2009 (Continued)

Incomplete outcome data (attrition bias) All outcomes	Low risk	Three patients in the ES and four each in the oxybutynin and placebo groups withdrew after randomisation, leaving 23 in the ES, 20 in the oxybutynin, and 19 in the placebo group who completed the study Reasons for withdrawal not reported. ITT analysis carried out “based on the data obtained from initially randomized 73 subjects.”
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Wise 1992

Methods	Study design: comparative (unclear if randomised) Multicentre or single-centre: single-centre Setting: UK Period: not reported Details of sample size calculation: not reported Follow-up: not reported
Participants	N: 40 recruited Mean (SD) age: not reported Sex: women Inclusion criteria: urodynamically proven idiopathic DO Exclusion criteria: not reported
Interventions	A (n = ?) ES. Daily session at home for 6 weeks with intravaginal maximal electrical stimulator B (n = ?) terodiline 25 mg daily for 6 weeks
Outcomes	Reduction in symptoms: urgency, frequency, urgency incontinence, stress incontinence
Notes	No data reported

Risk of bias

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported

Wise 1992 (Continued)

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not reported

Wise 1993

Methods	Study design: RCT Multicentre or single-centre: not reported Setting: UK Period: not reported Sample size: not reported Follow-up: 6 weeks
Participants	N: 60 randomised Sex: women Mean age: not reported Inclusion criteria: urodynamically proved DI Exclusion criteria: not reported
Interventions	A (n = 32) oxybutynin hydrochloride 5 mg B (n = 28) ES. 20-min sessions. Participants taught to insert vaginal electrodes and gradually increase stimulus to just below level of discomfort. Frequency 20 Hz, current 0-90 mA
Outcomes	Adverse effects: A 7/32. B 0/28
Notes	

Risk of bias

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Sixty women were recruited and randomised"
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported

Wise 1993 (Continued)

Incomplete outcome data (attrition bias) All outcomes	High risk	Differential dropout: "Nine patients in the oxybutynin group failed to complete the full treatment period. In seven cases this was due to unacceptable drug side effects. All patients in the MES group completed six weeks therapy and all found the method of treatment acceptable."
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Yamanishi 2000a

Methods	Study design: RCT Multicentre or single-centre: not reported Setting: Japan Period: not reported Sample size: not reported Follow-up: After 4-week treatment, participants who were cured or improved were followed up monthly on the basis of the records in the frequency/volume chart to evaluate post-stimulation effects. If the participant relapsed, the stimulation was repeated periodically in the same way using the same device until continence was regained
Participants	N: 68 randomised, 58 analysed Sex: 29 men and 39 women Mean age (range): 70 (35-87) Inclusion criteria: urinary incontinence due to DO Exclusion criteria: not reported
Interventions	A (n = 37) ES. Two 15-min sessions per day for 4 weeks Alternating pulses of 10-Hz square waves of 1-ms pulse duration and a maximum output current of 60 mA, stimulation up to maximum tolerable level B (n = 31) sham device identical to active device but with no stimulus output
Outcomes	Number of daytime voids (mean, N (SD not reported)): A 8, 32. B 7.5, 26 Number of nighttime voids (mean, N (SD not reported)): A 2, 32. B 2.3, 26 Number of leaks (mean, N (SD not reported)): A 1.2, 32. B 2.4, 26 Bladder capacity at first desire to void (mL) (mean, SD, N): A 174.2 (83.1), 32. B 130.0 (69.9), 26 Maximum cystometric capacity (mL) (mean, SD, N): A 285.0 (143.4), 32. B 182.9 (99.0), 26 Detrusor pressure at maximum sensation (cm H ₂ O) (mean, SD, N): A 34.6 (12.5), 32. B 50.9 (29.8). 26 Number of pad changes per 24 hours (mean, SD, N): A 0.8 (1.2), 37. B 1.1 (2.0), 31 Urgency score (0-3 scale: from 0 = none to 3 = very much) (mean, SD, N): A 1.7 (0.7), 37. B 2.0 (0.8), 31 Quality of life score (0-3 scale: from 0 = delighted to 3 = mostly dissatisfied) (mean, SD,

	<p>N): A 1.6 (0.7), 37. B 2.2 (0.9), 31 Number with DO: A 24/32, B 24/26 Number of participants with no improvement in DO: A 4/32 (FS1) . B 17/26 (FS2) Subjective impressions (very good or good, fair or not good): number of participants with fair or not good (i.e. not satisfied): A 13/32. B 17/26 Not cured (cure defined as "no incontinence on the frequency/volume chart and no detrusor overactivity according to cystometry") i.e. number of participants with UUI: A 25/32. B 25/26 Not improved (improvement defined as "if the frequency of the incontinence decreased by more than 50% compared with the baseline level or the cystometric capacity increased by more than 50 mL") i.e. number of participants with no improvement in UUI: A 6/26. B 19/28. (FS3) Adverse effects: A 2/37. B 2/31</p>
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Notes	No SDs
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Risk of bias *Risk of bias*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Patients were randomly assigned to either the active or the sham device."
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"The sham device was identical to the active device in appearance but with no stimulus output." "Neither doctors, nurses, nor patients knew which device was active or sham."
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	No differential attrition. "Four patients (three in the active group and one in the sham group) did not return after the first visit, and four patients (two at both groups) discontinued because of disagreeable feelings or vaginal pain"

Yamanishi 2000b

Methods	Study design: RCT Multicentre or single-centre: not reported Setting: Japan Period: not reported Details of sample size calculation: not reported Follow-up: single session
Participants	N: 32 randomised and analysed Mean (SD) age: A 66.8 (11.4). B 57.1 (20.1). Overall 62.3 (16.6) Sex: 15 men, 17 women Inclusion criteria: DO Exclusion criteria: not reported
Interventions	A (n = 17) functional ES. Alternating pulses of 10-Hz square waves 1 ms duration, maximum output current 60 mA. Stimulation up to maximum tolerable level. Device designed for home use. Surface electrodes for men (dorsal part of penis), vaginal plug for women B (n = 15) functional magnetic stimulation. Magnetic coil on armchair seat; perineum positioned to feel highest contraction of vaginal/anal sphincter. Intensity gradually increased up to tolerable limit, continuous eddy current 10 Hz, maximum output at the 100% setting of at least 270 J
Outcomes	Participants with DO: A 17/17. B 12/15 Bladder capacity at first desire to void, mL (mean, SD, N): A 220.4 (110.9), 17. B 225.1 (123.7), 15 Maximum cystometric capacity, mL (mean, SD, N): A 266.9 (151.0), 17. B 290.5 (146.3), 15 Detrusor pressure at maximum capacity, cmH ₂ O (mean, SD, N): A 15.4 (10.5), 17. B 13.9 (15.4), 15 Amplitude of detrusor overactive contraction, cmH ₂ O (mean, SD, N): A 51.3 (36.9), 17. B 51.5 (48.2), 15 Bladder compliance at maximum sensation, mL/ cmH ₂ O (mean, SD, N): A 24.3 (18.3), 17. B 32.7 (25.6), 15 Adverse effects: A 0/17. B 0/15
Notes	

Risk of bias

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"randomly assigned"
Allocation concealment (selection bias)	Unclear risk	"using envelopes containing a card indicating FES or FMS"

Yamanishi 2000b (Continued)

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	All randomised participants included in analysis. No withdrawals reported

AUASI: Americal Urological Association Symptom Index
 BAPFMT: biofeedback-assisted pelvic floor muscle training
 BMI: body mass index
 B-SAQ: Bladder Self-assessment questionnaire
 CI: confidence interval
 DH: detrusor hyperreflexia
 DI: detrusor instability
 DO: detrusor overactivity
 ES: electrical stimulation
 FDV: volume at first desire
 FES: functional electrical stimulation
 GSUI: stress urinary incontinence
 HRT: hormone replacement therapy
 ICIQ: International Consultation on Incontinence questionnaire (SF: short form)
 ICS: International Continence Society
 ITT: interferential therapy
 ITT analysis: intention-to-treat analysis
 IQR: interquartile range
 KHQ: King's Health Questionnaire
 LUTS: lower urinary tract symptoms
 MS: multiple sclerosis
 MUI: mixed urinary incontinence
 OAB: overactive bladder
 PFME: pelvic floor muscle exercises
 PFMT: Pelvic floor muscle training
 QoL: quality of life
 RCT: randomised controlled trial
 SANS: Stoller Afferent Neuro-stimulation
 SD: standard deviation
 SDV: strong desire to void
 SU: sensory urge
 SUI: stress urinary incontinence
 TENS: transcutaneous electrical nerve stimulation
 UI: urinary incontinence
 UTI: urinary tract infection
 UUI: urgency urinary incontinence
 VAS: visual analogue score

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Abdelghany 2001	Not RCT
Abel 1996	Not RCT
Al-Mulhim 2002	Not RCT
Almeida 2004	Not RCT
Angioli 2013	Not RCT
Baynham 2003	Not non-implanted device
Bazarim 2011	Not OAB
Bidmead 2002	Not OAB
Blok 2003	Not non-implanted device
Bocker 2002	Not OAB
Bolukbas 2005	Not RCT
Borawski 2007	Not non-implanted device
Bourcier 1994	Not OAB
Boy 2007	Not RCT
But 2003	Not electrical stimulation
Caputo 1993	Not RCT
Caraballo 2001	Not RCT
Casolati 2011	Not RCT
Chandi 2002	Not RCT
Congregado 2004	Not RCT
Das 2002	Not non-implanted device
De Laet 2005	Not RCT
Delneri 2000	Not OAB

(Continued)

Doganay 2010	Not RCT
Dunkley 2002	Not electrical stimulation
Edwards 1973	Not electrical stimulation
Edwards 2000	Not OAB
Elgamasy 1996	Not RCT
Esa 1991	Not RCT
Everaert 1999	Not OAB
Fall 1977	Not RCT
Fehrling 2007	Not RCT
Finazzi-Agró 2011	Not RCT
Franco 2011	Not RCT
Fujishiro 2002	Not electrical stimulation
Geirsson 1997	Not RCT
Glybochko 2010	Ineligible intervention
Govier 2001	Not RCT
Gungor 2011	Not RCT
Hasan 1994	Not non-implanted device
Hoffmann 2005	Not OAB
Holtedahl 1998	RCT of PFMT + ES + oestrogen versus 'wait' group. Women have SUI or undefined UI, but no definite diagnosis of OAB
Indrekvam 2001	Not RCT
Jacomo 2013	Not RCT
Jahr 2005	Not RCT
Karademir 2005	Ineligible comparison
Kaya 2011	Ineligible intervention

(Continued)

Kirschner-Hermanns 2003	Not RCT
Kralj 2001	Not RCT
Kölle 1995	Not RCT
Latini 2006	Not RCT
Lu 2012	Not RCT
Lucio 2013	Not OAB
MacDiarmid 2010a	Not RCT
MacDiarmid 2010b	Not RCT
Madersbacher 2004	Not RCT
Marcelissen 2011	Not RCT
Marchal 2011	Not RCT
Mauroy 2001	Not RCT
McClurg 2004	Not OAB
McClurg 2006	Not OAB
McClurg 2008	Not OAB
McGuire 2009	Not non-implanted device
McIntosh 1993	Not RCT
Memtsa 2009	Not RCT
Mok 2007	Not electrical stimulation
Moore 2003	Not electrical stimulation
NCT00534521 2007	Not OAB
NCT00547378 2007	Not non-implanted device
NCT00695058 2008	Withdrawn prior to enrolment
NCT00928499 2009	Not non-implantable device
NCT01023269 2009	Not non-implanted device

(Continued)

NCT01043848 2009	Not OAB
NCT01972061 2013	Not RCT
NCT02029027 2012	Not OAB
NCT02107820 2014	Ineligible comparator
NCT02176642 2014	Ineligible comparator
NCT02185235 2014	Not OAB
NCT02190851 2014	Not OAB
NCT02239796 2014	Not OAB
Neimark 2010	Not RCT
Nuhoglu 2006	Not RCT
Oh-Oka 2007	Not RCT
Okada 1998	Not RCT
Onal 2012	Not RCT
Ozdedeli 2010	Ineligible comparator
Parsons 2004	Not OAB
Pennisi 1994	Not RCT
Perissinotto 2013	Not OAB
Peters 2012	Not RCT
Petersen 1994	Not RCT
Polo 2012	Not RCT
Portigliotti 1996	Not RCT
Preisinger 1990	Not OAB
Rasero 2005	Not RCT
Reilly 2008	Not non-implanted device
Ricci 2004	Not non-implanted device

(Continued)

Sale 1994	Not electrical stimulation
Seif 2003	Not RCT
Seo 2004	Not OAB
Shafik 2004	Unclear if RCT/OAB
Shah 2012	Not RCT
Siegel 1997	Not RCT
Stein 1995	Not RCT
Surwit 2010	Not RCT
Suzuki 2007	Not electrical stimulation
Van Del Pal 2006	Not RCT
Van Meel 2012	Not RCT
Van-Balken 2001	Not RCT
Van-Balken 2006	Not RCT
Vandoninck 2004	Not RCT
Vecchioli-Scaldazza 1997	Not RCT
Veloso 2011	Not RCT
Voorham 2006	Not RCT
Voorham-Van Der Zalm 2007	Ineligible intervention and comparator is urodynamic evaluation only
Wallis 2006	Not electrical stimulation
Walsh 2000	Ineligible intervention
Webb 1992	Not non-implanted device
Wooldridge 2009	Not RCT
Yamanishi 2006	Not electrical stimulation
Yamanishi 2012	Not electrical stimulation
Yamanishi 2013	Not electrical stimulation

(Continued)

Yasar 2009	Not RCT
Yaski 2013	Not RCT
Yasuda 1994	Not OAB
Yokoyama 2004	Not RCT
Yoong 2010	Not RCT
Yoong 2013	Not RCT

ES: electrical stimulation

OAB: overactive bladder

PFMT: pelvic floor muscle training

RCT: randomised controlled trial

SUI: stress urinary incontinence

Characteristics of studies awaiting assessment *[ordered by study ID]*

Zhao 2000

Methods	
Participants	
Interventions	
Outcomes	
Notes	Awaiting translation

Characteristics of ongoing studies *[ordered by study ID]*

NCT01464372

Trial name or title	Electromagnetic Stimulation for the treatment of urge urinary incontinence and overactive bladder (ELEC STIM)
Methods	Study design: RCT Multicentre or single-centre: unclear Setting: USA Follow-up: unclear

NCT01464372 (Continued)

Participants	N: 130 Sex: women Inclusion criteria: age 18 +, UUI, urinary frequency Exclusion criteria: primary complaint of stress incontinence, neurogenic bladder, overflow incontinence, functional incontinence
Interventions	A: Electrical field stimulation device B: Sham nerve stimulation device
Outcomes	Reduction of incontinence episodes Serious adverse events or unanticipated adverse device effects
Starting date	October 2011
Contact information	info@emkinetics.com
Notes	Study terminated. Contacted manufacturer 20 February 2015

NCT01783392

Trial name or title	Peripheral Electrical Stimulation for the Treatment of Overactive Bladder (PESTOB)
Methods	Study design: RCT Multicentre or single-centre: Setting: Follow-up: 4 weeks
Participants	N: 36 Sex: men and women Inclusion criteria: at least 18 years of age, documented symptoms of idiopathic OAB for at least 3 months, failure of primary OAB treatment, such as behaviour modification or fluid/diet management, participants can remain on stable medication, willing and capable of understanding and complying with all requirements of the protocol Exclusion criteria: urinary retention or post voiding residual greater than 100 mL, clinically significant bladder outlet obstruction, stress predominant MUI, neurological disease affecting urinary bladder function, including but not limited to Parkinson's disease, multiple sclerosis, stroke, spinal cord injury, pelvic surgery (such as sub-urethral sling, pelvic floor repair) within the past 6 months, de novo OAB following pelvic surgery, sub-urethral sling, intravesical or urethral sphincter. Botulinum Toxin Type A injections within the past 6 months, PTNS therapy for overactive bladder within the past 6 months, any form of ES to the pelvis or lower limbs within 4 weeks, vaginal prolapse greater than Stage II in the anterior compartment of the vagina using ICS Pelvic Organ Prolapse Quantification (POPQ) criteria, prior periurethral or transurethral bulking agent injections for bladder problems within the past 12 months, history of pelvic radiation therapy, any skin conditions affecting treatment sites, lacking dexterity to properly utilise the components of the stimulator system, presence of an implanted electro-medical device (e.g. pacemaker, defibrillator, InterStim®, etc), pregnant, nursing, suspected to be pregnant (by urine pregnancy method), or plans to become pregnant during the course of the study, recurrent UTI (> 3 UTI's in the past year), history of, or current, lower tract genitourinary malignancies, any clinically significant systemic disease or condition that in the opinion of the Investigator would make the patient unsuitable for the study, any other clinical trial within 6 months

NCT01783392 (Continued)

Interventions	<p>A: Unilateral PTNS. 40 min every day for a duration of 4 weeks. The participant places the cathode electrode above, and the anode electrode behind the medial malleolus, over the posterior tibial nerve and sets the stimulation intensity to a comfortable level</p> <p>B: Bilateral PTNS. 40 min every day for a duration of 4 weeks. The participant places the cathode electrode above, and the anode electrode behind the medial malleolus, over the posterior tibial nerve on both legs and sets the stimulation intensity to a comfortable level</p> <p>C: Shoulder stimulation. 40 min every day for a duration of 4 weeks. The participant places the cathode and the anode electrodes on the lateral side of the left shoulder</p>
Outcomes	<p>Change in frequency of voiding</p> <p>Change in Patient Perception of Bladder Condition (PPBC)</p> <p>Changes in symptom severity score and health-related quality of life score (HRQL) based on OAB-Q</p> <p>Changes in the mental/physical scores of RAND36</p> <p>Change in urinary symptoms score and bother symptom score based on the ICIQ-OAB questionnaire</p>
Starting date	March 2013
Contact information	Martin Slovak m.slovak@sheffield.ac.uk
Notes	Contacted February 2015. Manuscript due for submission shortly

NCT01912885

Trial name or title	Comparison of posterior tibial nerve electrical stimulation protocols for overactive bladder syndrome
Methods	<p>Study design: RCT</p> <p>Multicentre or single-centre: unclear</p> <p>Setting: Brazil</p>
Participants	<p>N: 145</p> <p>Sex: women</p> <p>Inclusion criteria: age 18 +, cognitive level adequate for understanding orientations during treatment; clinical diagnosis of OAB syndrome for at least six months prior to the study</p> <p>Exclusion criteria: pregnant women or women who wish to get pregnant; neurological disease; urinary infection; nephrolithiasis; SUI; MUI; women in pharmacological treatment for OAB; women undergoing hormone replacement therapy in the last 6 months; peripheral neuropathy; cystocele stage two or higher</p>
Interventions	<p>A: Placebo: electrodes will be fixed to one leg and sessions will be held once a week</p> <p>B: ES on 1 leg once a week</p> <p>C: ES on 1 leg twice a week</p> <p>D: ES on 2 legs once a week</p> <p>E: ES on 2 legs once a week</p> <p>F: ES on 2 legs twice a week</p>
Outcomes	<p>Change in urinary frequency in 12 sessions</p> <p>Number of micturitions per day</p> <p>Change in nocturia in 12 sessions</p> <p>Number of micturitions per night, interrupting sleep</p>

NCT01912885 (Continued)

	Change in urinary urgency in 12 sessions Number of urgent micturitions per day Change in urinary urge-incontinence in 12 sessions Number of leaks per day
Starting date	March 2012
Contact information	Nanci Valeis nanci.valeis@hc.fm.usp.br PI Munick L Pierre
Notes	Currently recruiting participants

NCT01940367

Trial name or title	Electrical nerve stimulation for overactive bladder a comparison of treatments
Methods	Study design: RCT Multicentre or single-centre: unclear Setting: USA
Participants	N: 114 Sex: women Inclusion criteria: Female age >18 years, predominant complaint urge urinary incontinence (3 or more episodes per week) OR overactive bladder (8 or more voids per day, and/or 2 or more voids per night), failed trial of conservative therapy (bladder training, fluid modification, diet modification, caffeine restriction, pelvic floor training), failed trial of anticholinergic either due to inability to take the medication, adverse reaction to medication, or no improvement on medication, willing and mentally competent to participate in study, willing to complete study questionnaires, no contraindications to undergoing percutaneous tibial nerve stimulation or TENS therapy Exclusion criteria: Age < 18 years, presence of urinary fistula, recurrent or current urinary tract infection (5 or more infections in the last 12 months), bladder stones, bladder cancer or suspected bladder cancer, haematuria, pregnancy or planning to become pregnant during the study (urine pregnancy test will be administered to those who are premenopausal and who have not had a hysterectomy), central or peripheral neurologic disorders such as multiple sclerosis, Parkinson's disease, spina bifida, or other spinal cord lesion, metal implants such as pacemaker, implantable defibrillator, or metal implants where percutaneous tibial nerve stimulation or TENS device needs to be placed (sacrum or ankle/leg), uncontrolled diabetes, diabetes with peripheral nerve involvement, anticoagulants, current use of anticholinergics or use within the last 4 weeks, current use of botulinum toxin bladder injections or bladder botulinum toxin injection within the last year, current use of InterStim® therapy or currently implanted InterStim® device or leads, bladder outlet obstruction, urinary retention or gastric retention, painful bladder syndrome/interstitial cystitis
Interventions	A: PTNS once weekly for 30 min for 12 weeks. If at 12 weeks participants are considered to have a positive response to therapy, they will continue maintenance therapy in a tapered fashion: participants will come in every 2 weeks for the next 8 weeks for 30-min treatments (4 visits total), then every 3-4 weeks for 30-min treatments for the remaining 32 weeks of the year (8-10 visits) B: TENS. Home TENS device (EMPI TENS Select) and for self-treatment daily for 2 h per day (1 h in the morning and 1 h in the evening) for 12 weeks. If considered to have a positive response with TENS treatment at 12 weeks, participants will continue by weaning use over a 3-month time period, beginning with 3 x per

NCT01940367 (Continued)

	week for 1 month, then 2 x per week for 1 month, then 1 x per week for 1 month, all at 2 h per day
Outcomes	Success at 1 year, defined as a 50% or more reduction in the total number of incontinence episodes, or a 25% or more reduction in number of daily or nightly voids AND that the participant continues to use the therapy at 1 year. Therefore primary response is: 50% reduction in incontinence, OR 25% reduction in nightly voids AND continued use of therapy at 1 year Participant compliance defined as 75% adherence to the recommended use for each device Changes in the OAB-Q Changes in urodynamic studies
Starting date	October 2013
Contact information	PI Mary E McVearry Shannon Lamb, Physician, Walter Reed National Military Medical Centre
Notes	Due to complete December 2016

NCT02110680

Trial name or title	
Methods	RCT Setting: Israel Follow-up: 12 weeks
Participants	Estimated enrolment: 40 Inclusion criteria <ul style="list-style-type: none"> • men and women • age above 18 • OAB symptoms more than 6 months before run into the study • OAB symptoms refractory to medical oral and cognitive treatments • Adverse events or unwillingness to continue with above mentioned treatments • people with OAB symptoms with no evidence of neuropathic nature • people who signed informed consent fully understanding the treatment and study design Exclusion criteria: children, people who were unable to or did not sign an informed consent or do not understand the study design and the treatment, implanted electric devices (e.g. cardiac stimulators etc.), post voiding residual more than 100 mL, neuropathic OAB or pelvic ongoing malignancy or prior pelvic radiation, treated in the last 6 months with SNM, posterior tibial nerve stimulation or intravesical Botox injections, de novo OAB after recent implantation of tension-free vaginal tape (TVT) procedure, SUI predominant complaints in people with MUI, significant pelvic organ prolapse in women or an evidence of significant bladder outlet obstruction in male patients, history of recurrent UTIs during the last 2 years, any medical condition that involves skin on the lower extremity, bilateral leg amputation, any medical condition that in the investigator's opinion could have an adverse impact on the participant during the study, participation in a clinical study at the last 6 months
Interventions	TENS at posterior tibial nerve area Sham comparator: TENS at shoulder area

NCT02110680 (Continued)

Outcomes	Day and night-time frequency of micturitions OAB-Q Participant perception of bladder condition (PPBC) Participant perception of global improvement (PPGI) Quality of life 5 dimensions (EQ5D)
Starting date	April 2014 May 2015 - study withdrawn prior to enrolment
Contact information	Michael Vainrib, M.D. mvainrib@gmail.com
Notes	Estimated Study Completion Date:

NCT02311634

Trial name or title	
Methods	RCT Setting: China Follow-up: 4 weeks' treatment, 1 year follow-up
Participants	N = 80 Inclusion criteria <ul style="list-style-type: none"> ● Female, 25-85 years ● UUI history ● Positive pad test result ● Urodynamic study: a decrease in bladder capacity at the first desire for urination; a decrease in maximum bladder capacity; low compliance bladder Exclusion criteria <ul style="list-style-type: none"> ● UUI that can be relieved by drugs ● Neurogenic or non-neurogenic UUI ● Other types of incontinence such as SUI and overflow incontinence
Interventions	Electrical pudendal nerve stimulation at a frequency of 2.0 Hz and a moderate intensity (25-35 mA); 60 min 3 times a week for a total of 4 weeks Transvaginal ES at a current intensity of < 60 mA (as high as possible to get a contraction) and frequencies of 15 Hz and 85 Hz (alternate 3-min periods of stimulation); 20 min 3 times a week for a total of 4 weeks
Outcomes	Severity of UUI symptoms 24-hour urine leakage amount
Starting date	December 2014
Contact information	Xiaoming Feng, Ph.D fengtcm@126.com
Notes	Estimated Study Completion Date: Jan 2016

Trial name or title	
Methods	RCT Setting: UK Follow-up: 6 months
Participants	N = 24 Inclusion criteria <ul style="list-style-type: none"> • Women • Over 18 years of age • Clinically diagnosed with idiopathic OAB according to the definition by the ICS (Haylen et al, 2012) given above. • Good response to PTNS. For the purpose of this study, responders will be considered those participants who have achieved a reduction in the number of micturitions per 24 h by > 30% • Able and willing to give informed consent Exclusion criteria <ul style="list-style-type: none"> • Unable to comprehend the physiotherapist's instructions or unable to co-operate • Pregnancy, or plans of becoming pregnant during the course of the study. The main acupuncture point that will be used (SP6) has been reported to induce uterine activity (Hecker et al, 2001). • Presence of a relevant neurological condition (causing neurogenic DO or peripheral neuropathy) • Previous history of continence surgery • Women with a pacemaker fitted • Women with uncorrectable coagulopathies or on anticoagulant medication • Presence of dermatological lesions (e.g. dermatitis, eczema) in the medial aspect of lower leg and/or feet • No anticholinergic medication will be allowed during the study period with minimum wash-out period of 15 days before randomisation
Interventions	Percutaneous Stimulation PTNS performed bilaterally every 4 weeks within the Physiotherapy Department Transcutaneous Stimulation TPTNS applied bilaterally, using two surface, self-adhesive, round electrodes (3 cm in diameter) in each leg at least 3 times per week
Outcomes	Symptom severity measured by OAB-Q Changes in 24-hour micturition frequency Mean number of micturition episodes recorded in 3-day bladder chart
Starting date	February 2014
Contact information	Louise Hardman l.hardman@lwh.nhs.uk
Notes	Due to complete: Feb 2016

Trial name or title	
Methods	RCT Setting: Brazil Follow-up: 8 weeks' treatment, 3 months' follow-up
Participants	N = 30 Inclusion criteria - women with UUI or MUI older than 18 years Exclusion criteria <ul style="list-style-type: none"> • Presence of vaginal or urinary infection • Not able to understand or sign the informed consent • Not able to understand or unable to perform the proposed treatment • Pregnancy or the postpartum period covering the period up to 6 months after delivery • Women in previous use of chronically used drugs (antidepressants, diuretics, and others) that can evidently alter the urinary function. • SUI of pure or mixed incontinence with a predominance of stress component neurogenic bladder • Use of Botox® in the bladder or pelvic muscles in the last year • Use of Interstim® or Bion® • Use of pacemaker or implantable defibrillator • Current use of TENS in the pelvic region, lower back or legs • Previous use of percutaneous tibial stimulation • Drug/experimental devices in the past 4 weeks • Participation in any clinical research involving or affecting the urinary or renal function in the last 4 weeks • Pelvic radiotherapy • Changes in sensibility lower limb
Interventions	Transcutaneous electrical stimulation of the tibial nerve at home Development of an innovative portable equipment, with domestic technology for home application of the posterior tibial nerve stimulation technique using the type SSP surface electrodes (Silver Spike Point). Frequency: 20 Hz, Pulse width: 200 us; duration: 15 minutes daily Active Comparator: "Pelvic Floor Exercises": This group will do pelvic muscle training 3 times a day . In dorsal decubitus posture, legs flexed and abducted. Perform pelvic floor contractions keeping 2 seconds and relaxing 4 seconds for 10 times, and contractions keeping 4 seconds and relaxing 8 seconds for 10 times
Outcomes	Number of participants with UUI
Starting date	January 2014
Contact information	Magda Ms Aranchip mchipe@hotmail.com Luciana Dr Paiva luciana.paiva@ufrgs.br
Notes	Due to complete August 2015

Trial name or title	
Methods	RCT Setting: Brazil Follow-up: unclear
Participants	N = 12 Inclusion criteria <ul style="list-style-type: none"> • Female • Aged between 40 and 60 years • Clinical diagnosis of OAB syndrome non neurogenic type • Score questionnaire OAB-V8, sum equal to or greater than 8 • Calendar indicating voiding more than 8 micturitions in 24 hours • Complaints of urinary urgency Exclusion Criteria <ul style="list-style-type: none"> • With a diagnosis of lower UTI • Signs of leukorrhoea/diagnosis of vaginitis • Pregnant women • Diagnosed with cancer of bladder or other pelvic organs • With a history of pelvic radiotherapy • With change in the sensitivity of the pelvis and lower limbs region • With diabetes mellitus • With known neurologic diseases • Patients on medications that may affect the autonomic nervous system, including anticholinergics, alpha-adrenergic antagonists, tricyclic antidepressants, serotonin, antimuscarinic, beta-receptor agonists or antagonists and antihypertensive agents • Use of cardiac pacemakers
Interventions	A: TENS: 2 self-adhesive electrodes, one immediately behind the medial malleolus and the other 10 cm above will be used. Through a chain of 1 Hz, the aim is to correctly identify the tibial nerve. This position is confirmed with the rhythmic movement of the finger flexion. The frequency is then changed to 10 Hz, the pulse width set at 200 “microseconds” and adjusted according to the intensity threshold for each participant, below motor threshold. This current generator also has a device, the VIF (variation in intensity and frequency) that aims to ease the accommodation of sensory receptors and enhance its effects. The application time is 30 min B: Placebo: active current for 15 seconds by means of an apparatus also IBRAMED brand externally similar to that used in A. Two self-adhesive electrodes, one immediately behind the medial malleolus and the other 10 cm above will be used. The application time 30 min
Outcomes	Parasympathetic and sympathetic system values obtained from heart rate variability (HRV) after TENS application
Starting date	March 2014
Contact information	None given
Notes	Due to complete August 2014

NCT02511717

Trial name or title	
Methods	RCT Setting: Canada Follow-up: 12 weeks
Participants	N = 60 Inclusion criteria <ol style="list-style-type: none"> 1. Female, > 18 years of age, with the clinical diagnosis of OAB 2. Failure of behavioural measures and pharmacologic therapy to adequately control OAB symptoms 3. Baseline patient perception of bladder condition score of 2 or higher Exclusion criteria <ol style="list-style-type: none"> 1. Current or previous percutaneous or sacral neuromodulation therapy 2. Stress predominant urinary incontinence 3. Newly added bladder medication or dose change with the last 2 months (tamsulosin, silodosin, alfuzosin, terazosin, baclofen, diazepam, amitriptyline, imipramine, DDAVP, tolterodine, oxybutynin, fesoterodine, darifenacin, solifenacin, trospium, mirabegron) 4. Intravesical botulinum toxin use within the last 1 year 5. Implanted pacemaker or defibrillator 6. History of epilepsy 7. Unable or unwilling to commit to study treatment schedule 8. Pregnant, or possible pregnancy planned for the duration of the study period 9. Active skin disease of the lower legs (dermatitis, cellulitis, eczema, trauma) 10. Documented allergy to patch electrodes or their adhesive 11. Abnormal sensory function of the lower limb 12. Metallic implant within the lower limb
Interventions	Sham transcutaneous tibial nerve stimulation: transcutaneous stimulation in a location and with settings not related to the bladder nerves, 3 x/week for 30 min for 12 weeks. Patch electrodes applied posterior to the lateral malleolus, and 5-10 cm above the lateral malleolus of the same leg. Bipolar stimulation setting will be used, with a frequency of 10 Hz, 200 ms pulse, and the amplitude will be set a 1 mA. This will be done by the participants at home 3 x/week for 30 min, over 12 weeks Transcutaneous tibial nerve stimulation. Patch electrodes applied posterior to the medial malleolus, and 5-10 cm above the medial malleolus of the same leg, just behind the medial tibial edge. Bipolar stimulation setting will be used, with a frequency of 10 Hz, 200 ms pulse, and the amplitude will be titrated up to participant's maximum nonpainful tolerance (between 0.5-10 mA). This will be done by the participants at home 3 x/week for 30 min, over 12 weeks
Outcomes	OAB-Q SF Voiding diary 24-hour pad weights Physician assessment of treatment benefit
Starting date	November 2015
Contact information	None given
Notes	Due to complete Nov 2017

NCT02582151

Trial name or title	
Methods	RCT Setting: Canada Follow-up: 3 months
Participants	N = 60 Inclusion criteria <ul style="list-style-type: none"> • > 18 years of age, with a clinical condition associated with neurogenic bladder dysfunction (multiple sclerosis, Parkinson's disease, stroke, dementia, cerebral palsy, spinal cord injury) (27) • Failure of behavioural measures and/or pharmacologic therapy to adequately control neurogenic bladder symptoms Exclusion criteria <ul style="list-style-type: none"> • Current or previous percutaneous/transcutaneous tibial nerve stimulation or sacral neuromodulation therapy • Stress predominant urinary incontinence • Newly added bladder medication or dose change with the last 2 months (tamsulosin, silodosin, alfuzosin, terazosin, baclofen, diazepam, amitriptyline, imipramine, DDAVP, tolterodine, oxybutynin, fesoterodine, darifenacin, solifenacin, trospium, mirabegron) • Intravesical botulinum toxin use within the last 1 year • Implanted pacemaker or defibrillator • History of epilepsy • Unable or unwilling to commit to study treatment schedule • Pregnant, or possible pregnancy planned for the duration of the study period • Active skin disease of the lower legs (dermatitis, cellulitis, eczema, trauma) • Documented allergy to patch electrodes or their adhesive • Metallic implant within the lower limb
Interventions	Sham tibial nerve stimulation Use of peripheral nerve stimulator in a location that will not actively stimulate the tibial nerve Tibial nerve stimulation Transcutaneous peripheral nerve stimulator in a location that will actively stimulate the tibial nerve Device: EV-906 Digital Transcutaneous electrical nerve stimulation (TENS) machine Percutaneous patch electrodes are used to deliver low level electrical currents
Outcomes	Neurogenic bladder symptom score questionnaire Qualiveen-Short Form Questionnaire Participant-reported urinary frequency, urgency, incontinence episodes 24-hour incontinence pad weights Physician assessment of participant benefit
Starting date	December 2015
Contact information	Mary McKibbon mary.mckibbon@sjhc.london.on.ca
Notes	Due to complete Dec 2016

NCT02583529

Trial name or title	
Methods	RCT Setting: Brazil Follow-up: 12 weeks
Participants	N = 30 Inclusion criteria <ul style="list-style-type: none">• Female, age 40-90• Clinical diagnosis of PD according to the criteria of the London Brain Bank• urinary storage symptoms complaints such as urinary urgency (sudden urge, abrupt and compelling, to urinate, which is difficult to suppress), with or without urge incontinence (urine leakage after emergency), frequency (number of urinations > 7/day) and nocturia (the number of micturitions > 1/night) Exclusion criteria <ul style="list-style-type: none">• Damage to the peripheral sacral nerves• Infection of the lower urinary tract untreated• Diabetes mellitus• Chronic pulmonary disease worsened• Pregnancy and postpartum• Urinary Incontinence of pure SUI or MUI with predominance of the stress component• Pacemaker or defibrillator• Metal prostheses• Application of botulinum toxin into the bladder and/or pelvic muscles within the last year• Current TENS treatment in the pelvic region, lower back and/or legs• Prior urinary incontinence surgery• Current bladder carcinoma• Cognitive impairment likely to prevent implementation of the proposed treatment• Not able to understand/sign informed consent
Interventions	Back Tibial Nerve Electrostimulation The BTNE will be made with electrodes Silver Spike Point (SSP) set in an ankle with the negative pole positioned on the inner malleolus and the positive approximately 0.5 cm below the previous, and connected to a portable stimulator powered by rechargeable battery developed by the Biomedical Engineering Department of the HCPA Placebo ES
Outcomes	Hoehn and Yahr Disability Stage of scale
Starting date	July 2014
Contact information	Tatiane Gomes de Araujo tatinhaga@yahoo.com.br
Notes	Due to complete December 2017

NTR2192

Trial name or title	
Methods	Study design: RCT Multicentre or single-centre: not reported Setting: the Netherlands Period: planned to be April 2009-October 2010 Details of sample size calculation: not reported Follow-up: 12 weeks
Participants	Inclusion criteria: OAB, defined as urgency and frequency (more than 8 voids per 24 h and the sudden urge to void can hardly be suppressed); urgency incontinence (urgency leading to urinary leakage occurring at least 3 times weekly); age > 18 years Exclusion criteria: symptoms existing for less than 6 months; pregnancy; active UTI or recurrent UTI; severe cardiopulmonary disease; diabetes with peripheral nerve involvement; neurological disorders; flowmetry < 15 mm/s; previous treatment for OAB
Interventions	1. PTNS 2. Bladder training
Outcomes	Primary outcomes: ICIQ-UI-SF scores; percentage of 70% improvement on the ICIQ-UI-SF scores Secondary outcomes: incontinence episodes per week; frequency of micturition per 24 h
Starting date	
Contact information	
Notes	Contacted study author asking for data 06 January 2015

DO: detrusor overactivity

ES: electrical stimulation

ICIQ: International Consultation on Incontinence Questionnaire

ICIQ-UI SF: International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form

MUI: mixed urinary incontinence

OAB: overactive bladder

RCT: randomised controlled trial

SUI: stress urinary incontinence

PTNS: posterior tibial nerve stimulation

TPTNS: transcutaneous posterior tibial nerve stimulation

TEVS: transcutaneous electrical nerve stimulation

UUI: urgency urinary incontinence

DATA AND ANALYSES

Comparison 1. Electrical stimulation (ES) versus no active treatment

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Number of participants cured or improved	2	121	Risk Ratio (M-H, Fixed, 95% CI)	1.85 [1.34, 2.55]

Comparison 2. Electrical stimulation (ES) versus placebo or sham treatment

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Number of participants cured	4	189	Risk Ratio (M-H, Fixed, 95% CI)	2.69 [1.39, 5.21]
2 Number of participants cured or improved	10	677	Risk Ratio (M-H, Fixed, 95% CI)	2.26 [1.85, 2.77]
3 Number of participants cured or improved: different ES routes	6	398	Risk Ratio (M-H, Fixed, 95% CI)	3.55 [2.54, 4.96]
3.1 Percutaneous tibial nerve stimulation	4	304	Risk Ratio (M-H, Fixed, 95% CI)	3.19 [2.22, 4.58]
3.2 Intravaginal	2	94	Risk Ratio (M-H, Fixed, 95% CI)	5.46 [2.33, 12.81]
4 Number of participants satisfied	2	98	Risk Ratio (M-H, Fixed, 95% CI)	1.44 [1.02, 2.04]
5 Number of participants with improvement in urgency urinary incontinence	2	242	Risk Ratio (M-H, Random, 95% CI)	5.03 [0.28, 89.88]
6 Number of participants with improvement in urinary frequency	2	236	Risk Ratio (M-H, Fixed, 95% CI)	2.04 [1.43, 2.92]
7 Number of incontinence episodes per 24 h	2	143	Mean Difference (IV, Fixed, 95% CI)	-1.43 [-1.92, -0.95]
8 Number of nocturia episodes	2	245	Mean Difference (IV, Fixed, 95% CI)	-0.37 [-0.73, -0.02]
9 Number of micturitions per 24 h	3	285	Mean Difference (IV, Fixed, 95% CI)	-1.09 [-1.70, -0.47]
10 Number of participants with adverse effects	3	450	Risk Ratio (M-H, Fixed, 95% CI)	1.24 [0.84, 1.83]

Comparison 3. Electrical stimulation (ES) versus pelvic floor muscle training (PFMT)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Number of participants cured or improved	3	195	Risk Ratio (M-H, Fixed, 95% CI)	1.60 [1.19, 2.14]
2 Number of participants satisfied	2	102	Risk Ratio (M-H, Fixed, 95% CI)	0.76 [0.60, 0.96]

Comparison 4. Electrical stimulation (ES) versus laserpuncture/electro-acupuncture

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Number of incontinence episodes per 24 h	2	136	Mean Difference (IV, Fixed, 95% CI)	-1.84 [-2.33, -1.35]

Comparison 5. Electrical stimulation (ES) versus drug therapy

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Number of participants cured	7	388	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.69, 1.41]
1.1 ES versus tolterodine	3	210	Risk Ratio (M-H, Fixed, 95% CI)	0.82 [0.46, 1.47]
1.2 ES versus oxybutynin	3	140	Risk Ratio (M-H, Fixed, 95% CI)	1.06 [0.65, 1.72]
1.3 ES versus propantheline bromide	1	38	Risk Ratio (M-H, Fixed, 95% CI)	1.48 [0.38, 5.74]
2 Number of participants cured or improved	8	439	Risk Ratio (M-H, Fixed, 95% CI)	1.20 [1.04, 1.38]
2.1 ES versus tolterodine	3	210	Risk Ratio (M-H, Fixed, 95% CI)	1.18 [1.00, 1.41]
2.2 ES versus oxybutynin	4	191	Risk Ratio (M-H, Fixed, 95% CI)	1.17 [0.91, 1.52]
2.3 ES versus propantheline bromide	1	38	Risk Ratio (M-H, Fixed, 95% CI)	1.44 [0.86, 2.44]
3 Number of participants cured or improved: routes of ES	5	250	Risk Ratio (M-H, Fixed, 95% CI)	1.26 [1.04, 1.54]
3.1 Transcutaneous posterior tibial nerve stimulation	1	51	Risk Ratio (M-H, Fixed, 95% CI)	1.20 [0.74, 1.92]
3.2 Intravaginal/transanal	4	199	Risk Ratio (M-H, Fixed, 95% CI)	1.28 [1.03, 1.59]
4 Number of participants satisfied	2	94	Risk Ratio (M-H, Fixed, 95% CI)	0.89 [0.64, 1.23]
4.1 ES versus oxybutynin	2	94	Risk Ratio (M-H, Fixed, 95% CI)	0.89 [0.64, 1.23]
5 Number of incontinence episodes per 24 h	5	477	Mean Difference (IV, Random, 95% CI)	0.25 [-1.11, 1.60]
5.1 ES versus tolterodine	1	84	Mean Difference (IV, Random, 95% CI)	-0.60 [-1.49, 0.29]
5.2 ES versus oxybutynin	1	43	Mean Difference (IV, Random, 95% CI)	0.90 [-6.45, 8.25]
5.3 ES versus trospium + solifenacin	1	110	Mean Difference (IV, Random, 95% CI)	2.2 [1.78, 2.62]

5.4 ES versus oestrogen cream	1	210	Mean Difference (IV, Random, 95% CI)	0.0 [-0.16, 0.16]
5.5 ES versus solifenacin succinate	1	30	Mean Difference (IV, Random, 95% CI)	-0.90 [-2.01, 0.21]
6 Number of urgency episodes per 24h	2	294	Mean Difference (IV, Fixed, 95% CI)	0.62 [0.28, 0.96]
6.1 ES versus tolterodine	1	84	Mean Difference (IV, Fixed, 95% CI)	-0.60 [-1.98, 0.78]
6.2 ES versus oestrogen cream	1	210	Mean Difference (IV, Fixed, 95% CI)	0.70 [0.35, 1.05]
7 Number of micturitions per 24 h	6	646	Mean Difference (IV, Fixed, 95% CI)	0.33 [0.15, 0.52]
7.1 ES versus tolterodine	2	116	Mean Difference (IV, Fixed, 95% CI)	0.22 [-1.06, 1.50]
7.2 ES versus oxybutynin	2	80	Mean Difference (IV, Fixed, 95% CI)	0.87 [-0.18, 1.91]
7.3 ES versus solifenacin succinate	1	30	Mean Difference (IV, Fixed, 95% CI)	-0.60 [-2.04, 0.84]
7.4 ES versus oestrogen cream	1	420	Mean Difference (IV, Fixed, 95% CI)	0.33 [0.15, 0.52]
8 Number of nocturia episodes per night	4	367	Mean Difference (IV, Fixed, 95% CI)	-2.07 [-2.27, -1.88]
8.1 ES versus tolterodine	1	84	Mean Difference (IV, Fixed, 95% CI)	-0.20 [-0.78, 0.38]
8.2 ES versus oxybutynin	1	43	Mean Difference (IV, Fixed, 95% CI)	0.30 [-0.35, 0.95]
8.3 ES versus solifenacin succinate	1	30	Mean Difference (IV, Fixed, 95% CI)	-0.20 [-1.06, 0.66]
8.4 ES versus oestrogen cream	1	210	Mean Difference (IV, Fixed, 95% CI)	-2.8 [-3.03, -2.57]
9 Number of participants with adverse effects	7		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
9.1 ES versus oxybutynin	2	79	Risk Ratio (M-H, Fixed, 95% CI)	0.11 [0.01, 0.84]
9.2 ES versus tolterodine	4	200	Risk Ratio (M-H, Fixed, 95% CI)	0.12 [0.05, 0.27]
9.3 ES versus solifenacin succinate	1	100	Risk Ratio (M-H, Fixed, 95% CI)	0.09 [0.01, 1.60]

Comparison 6. Electrical stimulation (ES) plus pelvic floor muscle training (PFMT) versus PFMT alone

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Number of participants satisfied	2	82	Risk Ratio (M-H, Fixed, 95% CI)	1.58 [1.13, 2.20]
2 Number of incontinence episodes per 24h	2	119	Mean Difference (IV, Random, 95% CI)	-0.60 [-1.84, 0.64]
3 Number of urgency episodes per 24 h	2	248	Mean Difference (IV, Fixed, 95% CI)	-2.49 [-2.74, -2.24]
4 Number of micturitions per 24 h	2	63	Mean Difference (IV, Fixed, 95% CI)	-0.75 [-1.62, 0.12]

Comparison 7. Electrical stimulation (ES) plus drug therapy versus drug therapy alone

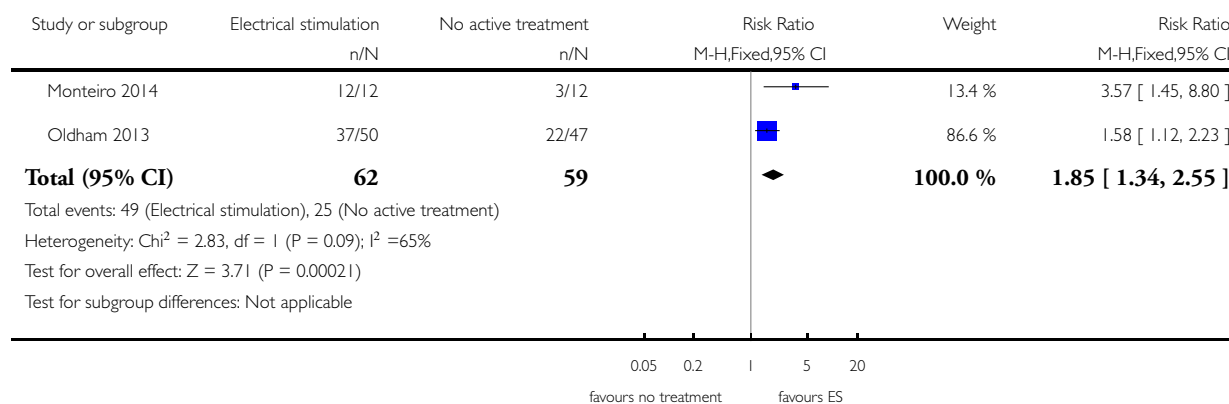
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Quality of life	2	248	Std. Mean Difference (IV, Random, 95% CI)	-1.50 [-3.72, 0.72]
2 Number of incontinence episodes per 24h	2	248	Mean Difference (IV, Fixed, 95% CI)	-0.53 [-0.63, -0.43]
3 Number of urgency episodes per 24 hours	2	248	Mean Difference (IV, Random, 95% CI)	-2.33 [-3.11, -1.54]
4 Number of micturitions per 24 hours	2	250	Mean Difference (IV, Fixed, 95% CI)	-0.01 [-0.22, 0.21]

Analysis 1.1. Comparison 1 Electrical stimulation (ES) versus no active treatment, Outcome 1 Number of participants cured or improved.

Review: Electrical stimulation with non-implanted electrodes for overactive bladder in adults

Comparison: 1 Electrical stimulation (ES) versus no active treatment

Outcome: 1 Number of participants cured or improved

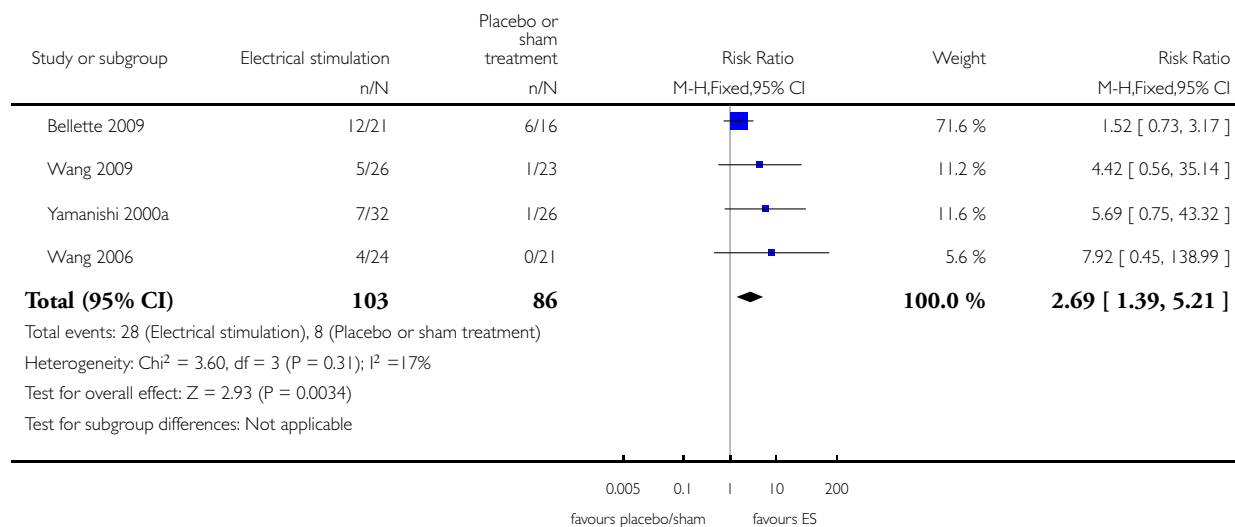


Analysis 2.1. Comparison 2 Electrical stimulation (ES) versus placebo or sham treatment, Outcome 1 Number of participants cured.

Review: Electrical stimulation with non-implanted electrodes for overactive bladder in adults

Comparison: 2 Electrical stimulation (ES) versus placebo or sham treatment

Outcome: 1 Number of participants cured

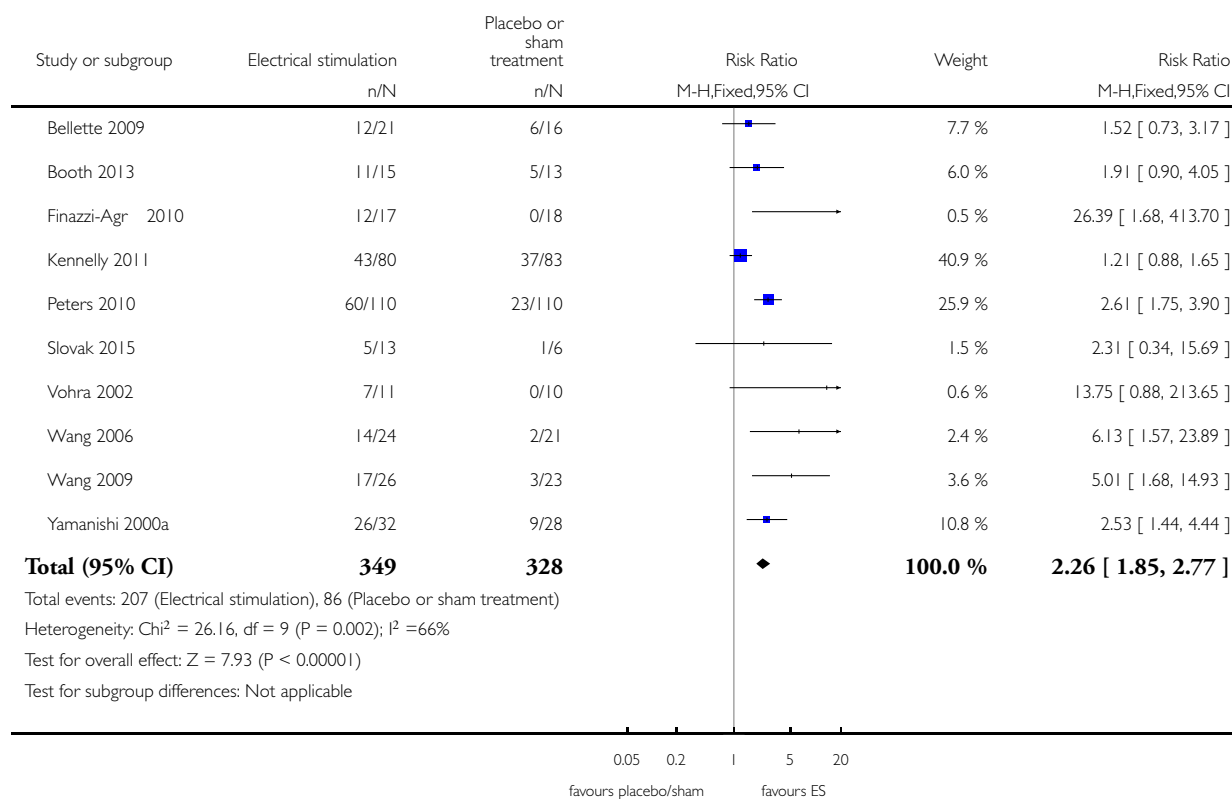


Analysis 2.2. Comparison 2 Electrical stimulation (ES) versus placebo or sham treatment, Outcome 2 Number of participants cured or improved.

Review: Electrical stimulation with non-implanted electrodes for overactive bladder in adults

Comparison: 2 Electrical stimulation (ES) versus placebo or sham treatment

Outcome: 2 Number of participants cured or improved

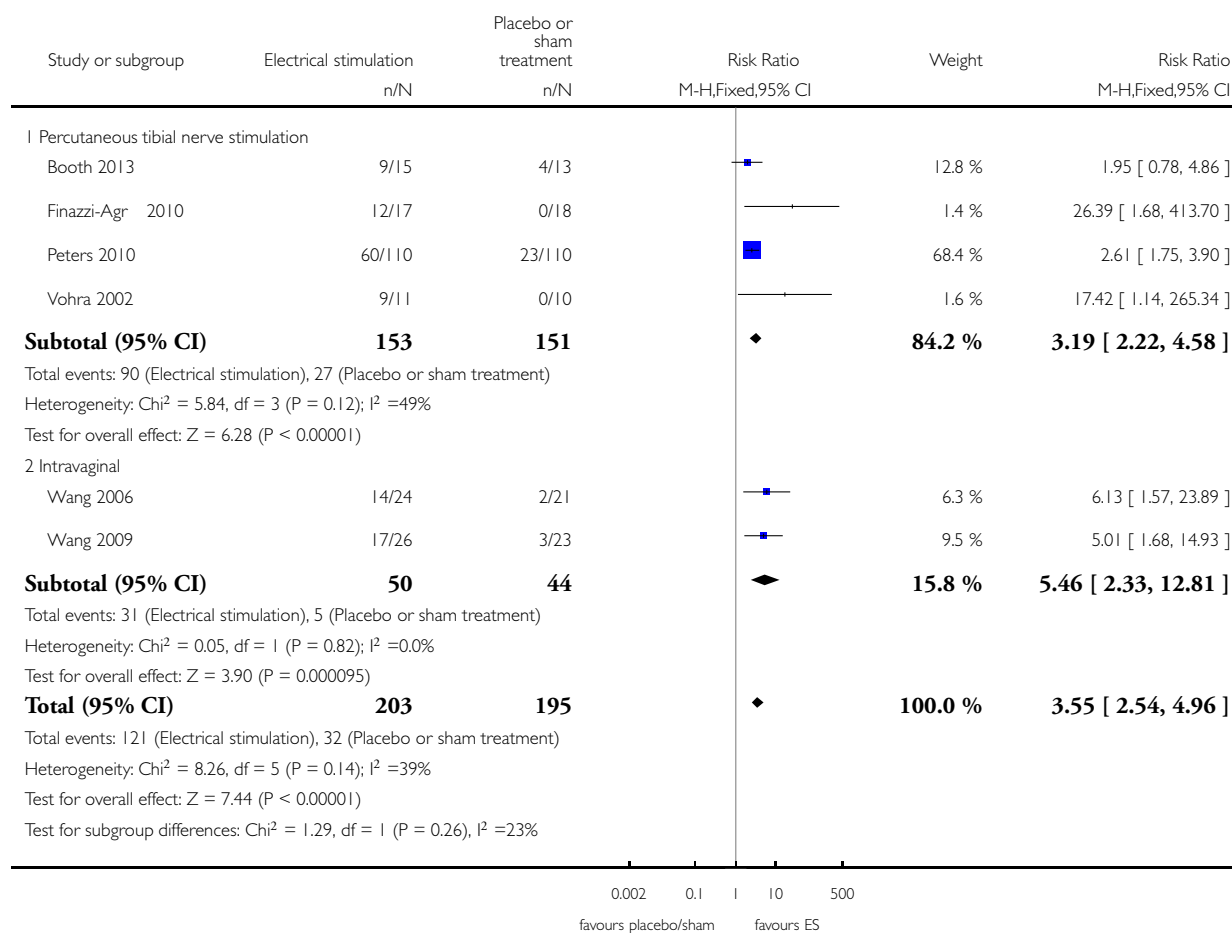


Analysis 2.3. Comparison 2 Electrical stimulation (ES) versus placebo or sham treatment, Outcome 3 Number of participants cured or improved: different ES routes.

Review: Electrical stimulation with non-implanted electrodes for overactive bladder in adults

Comparison: 2 Electrical stimulation (ES) versus placebo or sham treatment

Outcome: 3 Number of participants cured or improved: different ES routes

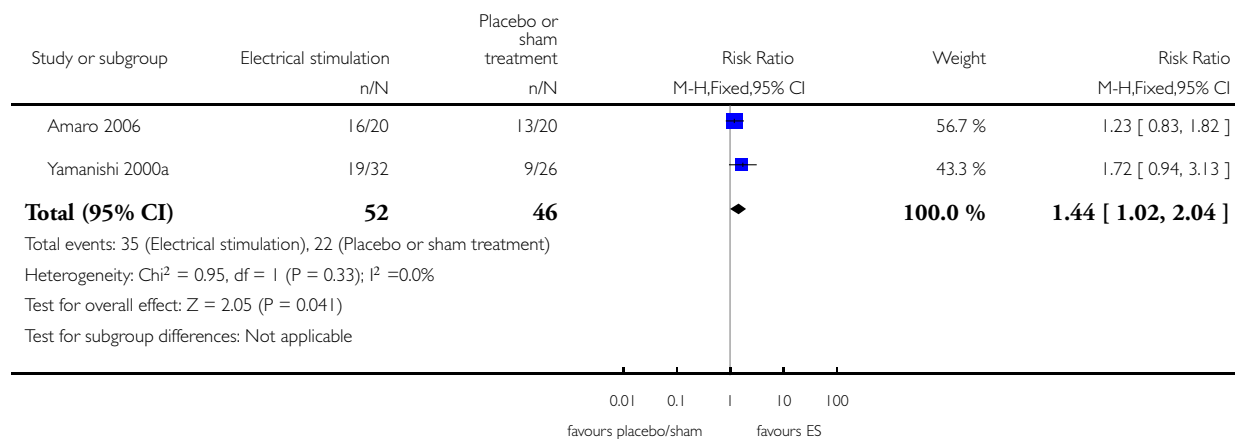


Analysis 2.4. Comparison 2 Electrical stimulation (ES) versus placebo or sham treatment, Outcome 4 Number of participants satisfied.

Review: Electrical stimulation with non-implanted electrodes for overactive bladder in adults

Comparison: 2 Electrical stimulation (ES) versus placebo or sham treatment

Outcome: 4 Number of participants satisfied

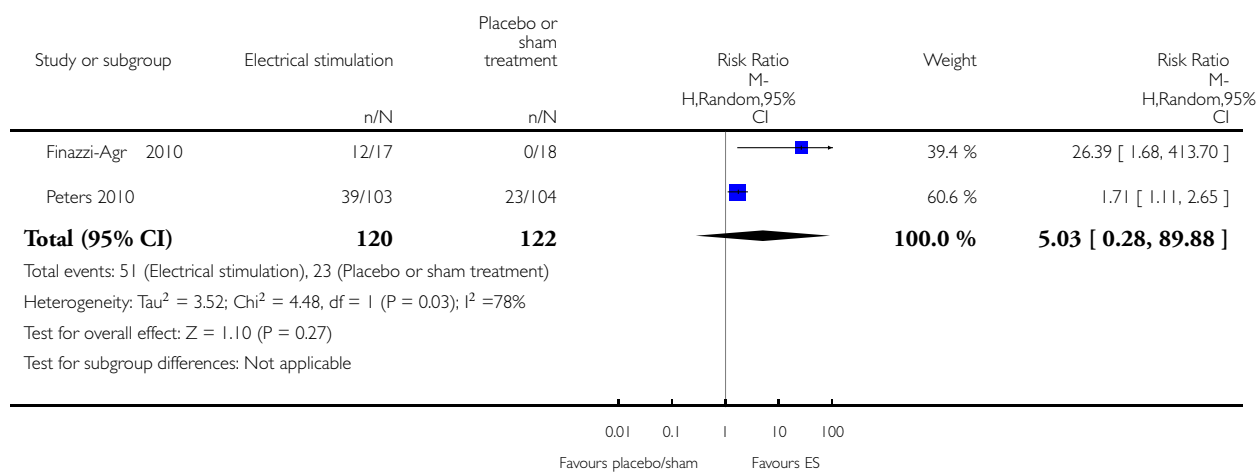


Analysis 2.5. Comparison 2 Electrical stimulation (ES) versus placebo or sham treatment, Outcome 5 Number of participants with improvement in urgency urinary incontinence.

Review: Electrical stimulation with non-implanted electrodes for overactive bladder in adults

Comparison: 2 Electrical stimulation (ES) versus placebo or sham treatment

Outcome: 5 Number of participants with improvement in urgency urinary incontinence

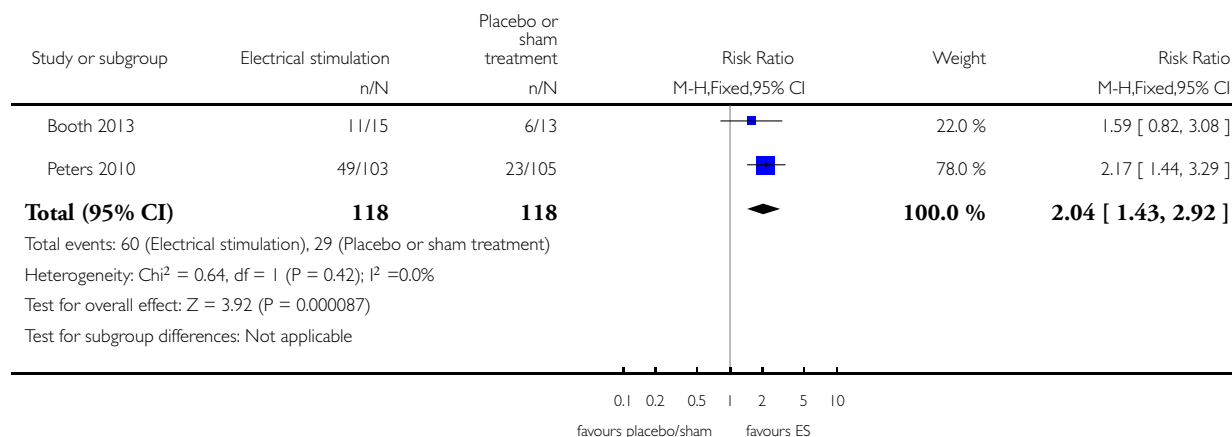


Analysis 2.6. Comparison 2 Electrical stimulation (ES) versus placebo or sham treatment, Outcome 6 Number of participants with improvement in urinary frequency.

Review: Electrical stimulation with non-implanted electrodes for overactive bladder in adults

Comparison: 2 Electrical stimulation (ES) versus placebo or sham treatment

Outcome: 6 Number of participants with improvement in urinary frequency

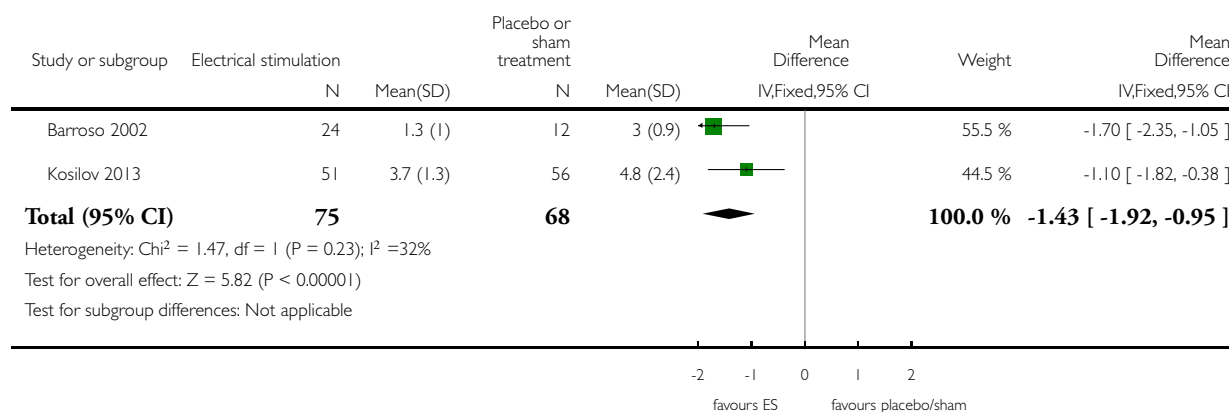


Analysis 2.7. Comparison 2 Electrical stimulation (ES) versus placebo or sham treatment, Outcome 7 Number of incontinence episodes per 24 h.

Review: Electrical stimulation with non-implanted electrodes for overactive bladder in adults

Comparison: 2 Electrical stimulation (ES) versus placebo or sham treatment

Outcome: 7 Number of incontinence episodes per 24 h

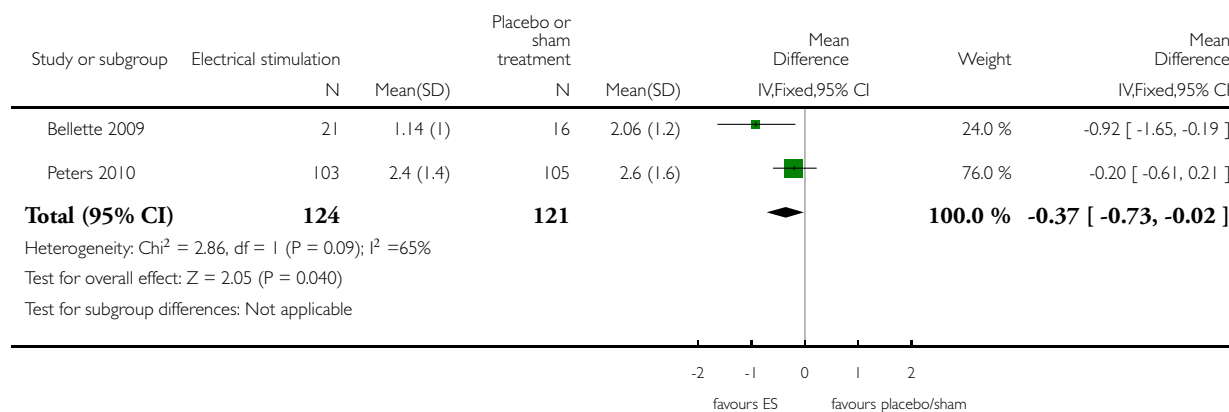


Analysis 2.8. Comparison 2 Electrical stimulation (ES) versus placebo or sham treatment, Outcome 8 Number of nocturia episodes.

Review: Electrical stimulation with non-implanted electrodes for overactive bladder in adults

Comparison: 2 Electrical stimulation (ES) versus placebo or sham treatment

Outcome: 8 Number of nocturia episodes

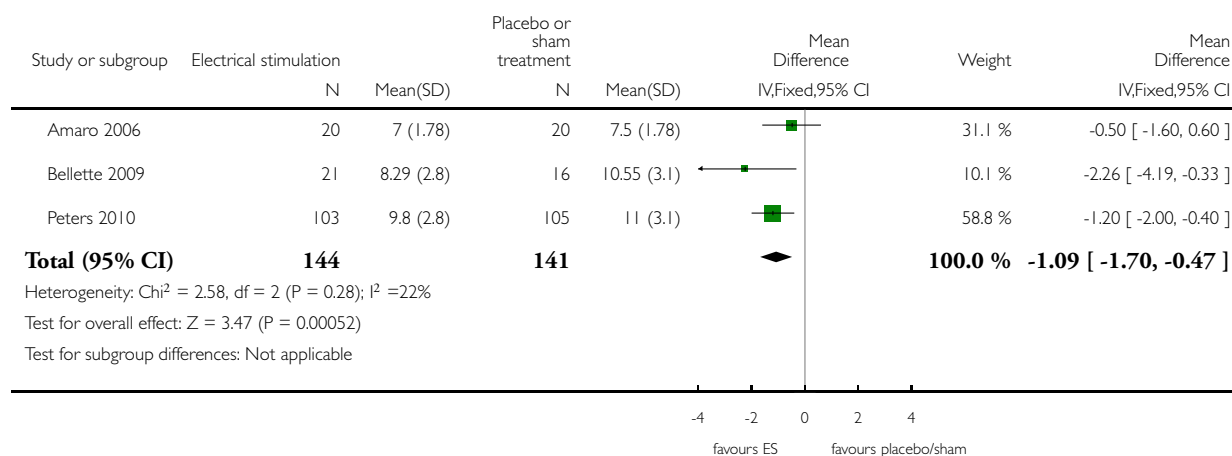


Analysis 2.9. Comparison 2 Electrical stimulation (ES) versus placebo or sham treatment, Outcome 9 Number of micturitions per 24 h.

Review: Electrical stimulation with non-implanted electrodes for overactive bladder in adults

Comparison: 2 Electrical stimulation (ES) versus placebo or sham treatment

Outcome: 9 Number of micturitions per 24 h

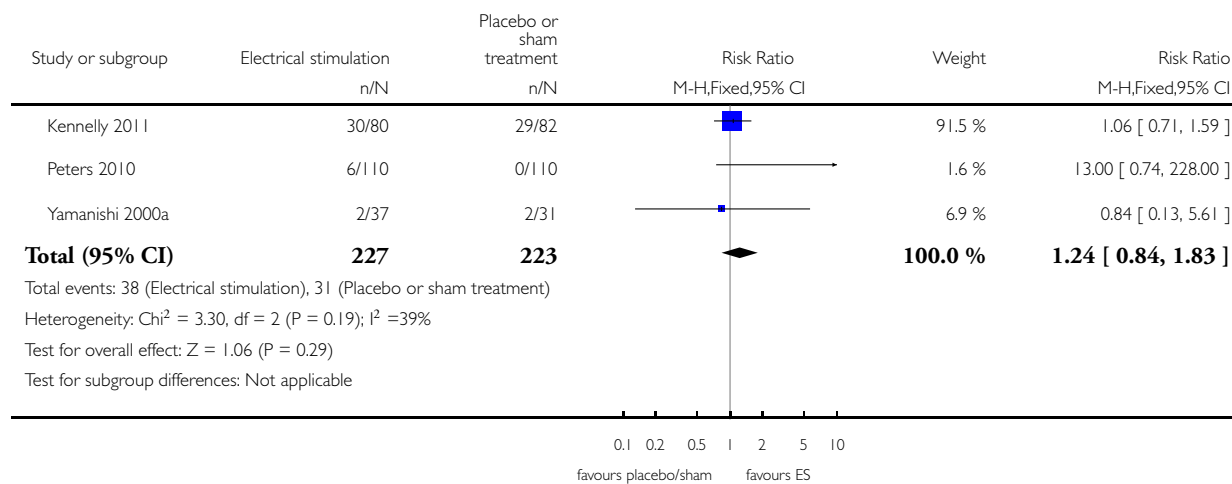


Analysis 2.10. Comparison 2 Electrical stimulation (ES) versus placebo or sham treatment, Outcome 10 Number of participants with adverse effects.

Review: Electrical stimulation with non-implanted electrodes for overactive bladder in adults

Comparison: 2 Electrical stimulation (ES) versus placebo or sham treatment

Outcome: 10 Number of participants with adverse effects

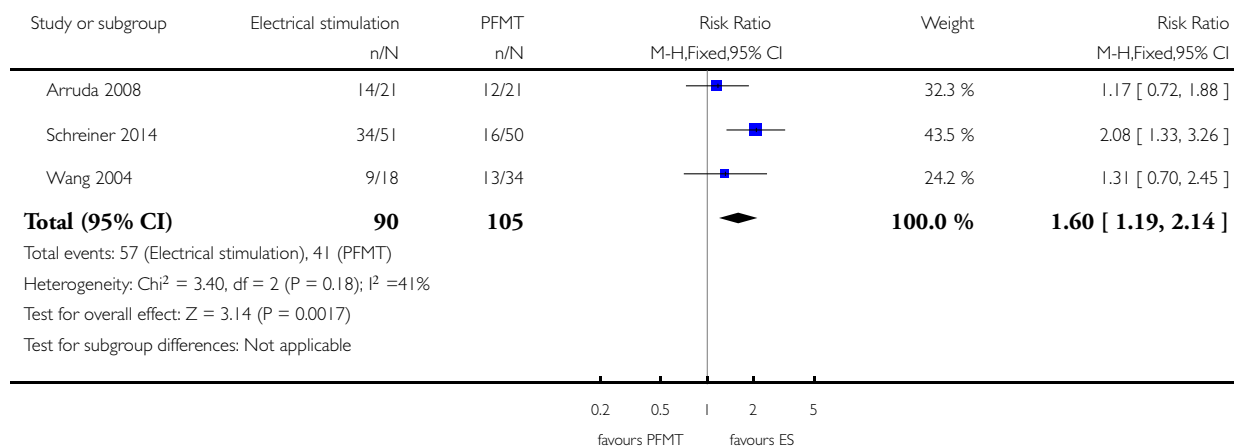


Analysis 3.1. Comparison 3 Electrical stimulation (ES) versus pelvic floor muscle training (PFMT), Outcome 1 Number of participants cured or improved.

Review: Electrical stimulation with non-implanted electrodes for overactive bladder in adults

Comparison: 3 Electrical stimulation (ES) versus pelvic floor muscle training (PFMT)

Outcome: 1 Number of participants cured or improved

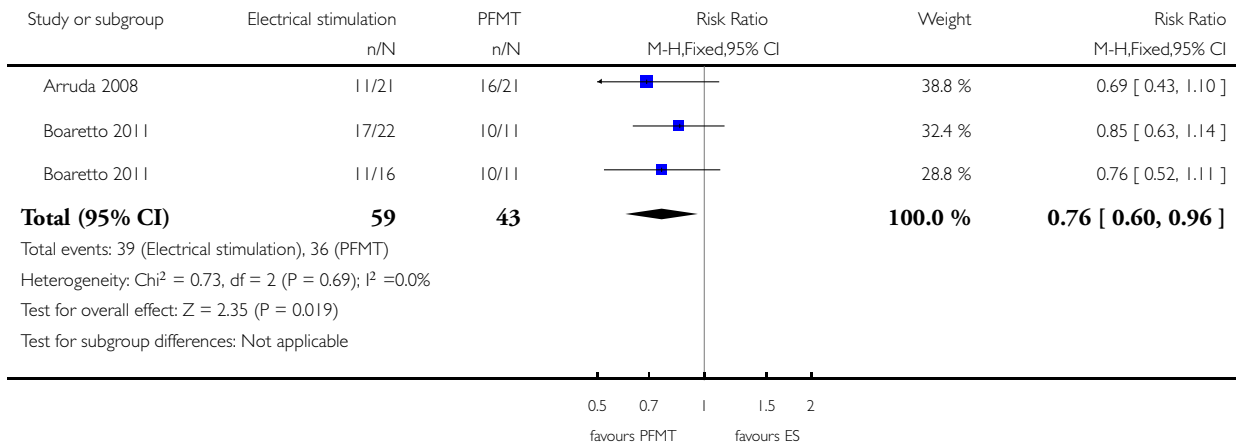


Analysis 3.2. Comparison 3 Electrical stimulation (ES) versus pelvic floor muscle training (PFMT), Outcome 2 Number of participants satisfied.

Review: Electrical stimulation with non-implanted electrodes for overactive bladder in adults

Comparison: 3 Electrical stimulation (ES) versus pelvic floor muscle training (PFMT)

Outcome: 2 Number of participants satisfied

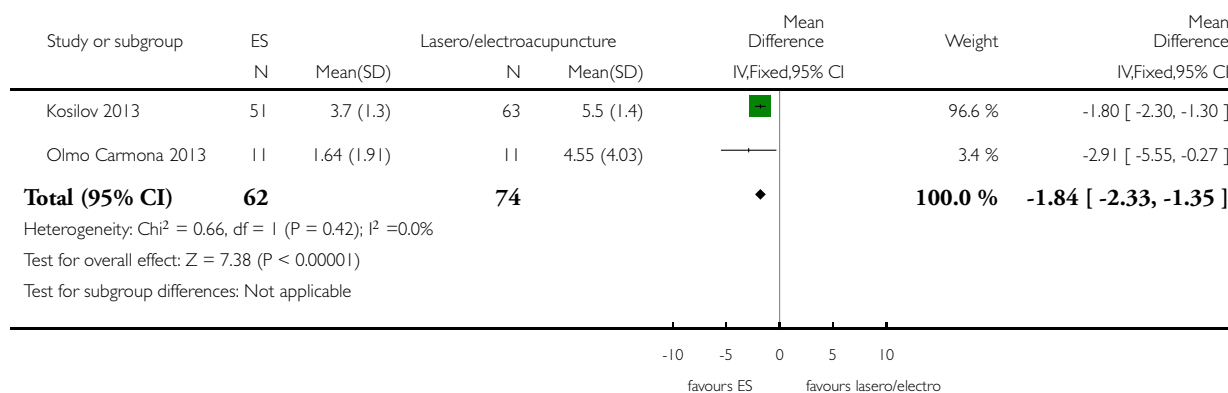


Analysis 4.1. Comparison 4 Electrical stimulation (ES) versus laseropuncture/electro-acupuncture, Outcome 1 Number of incontinence episodes per 24 h.

Review: Electrical stimulation with non-implanted electrodes for overactive bladder in adults

Comparison: 4 Electrical stimulation (ES) versus laseropuncture/electro-acupuncture

Outcome: 1 Number of incontinence episodes per 24 h

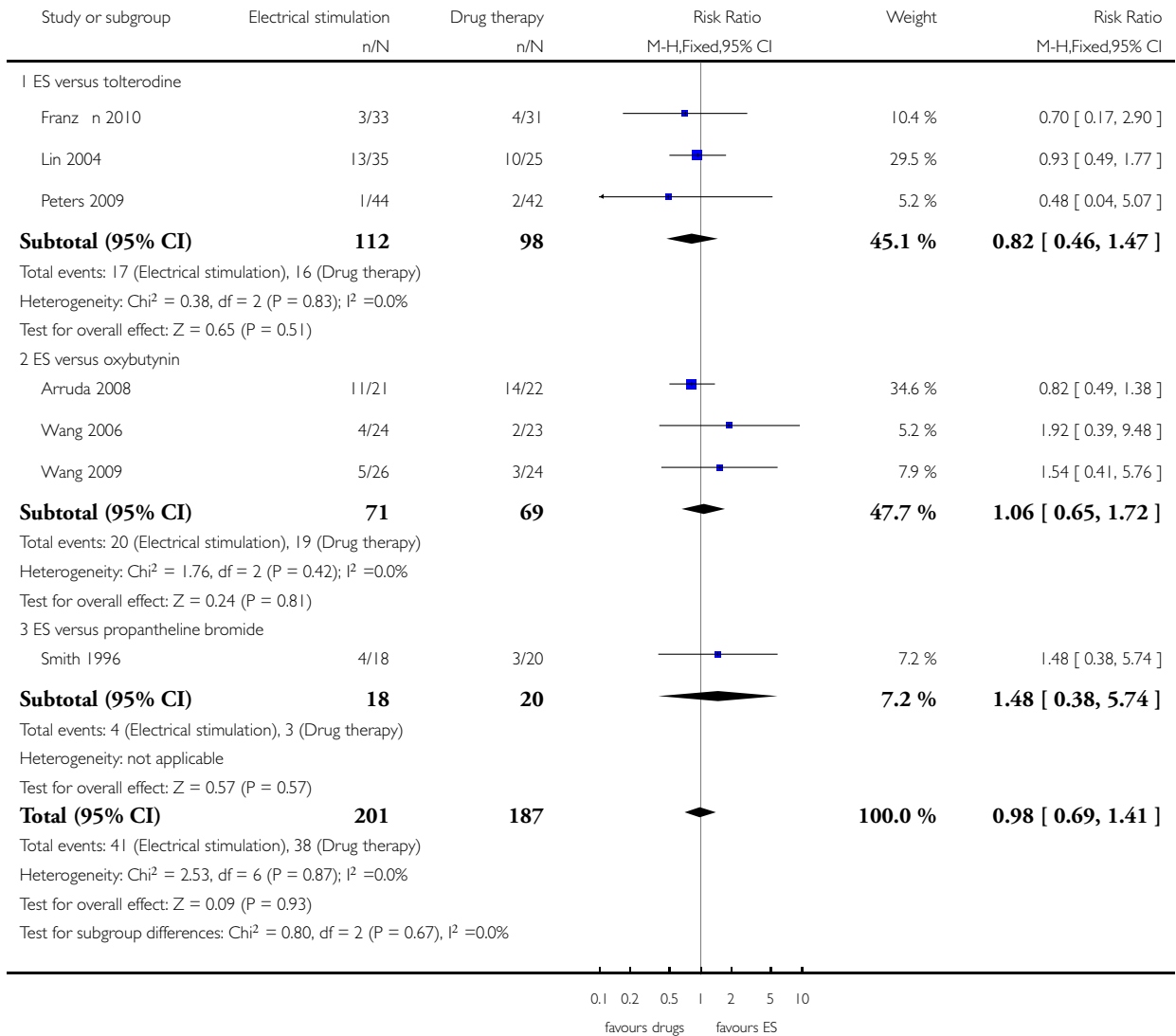


Analysis 5.1. Comparison 5 Electrical stimulation (ES) versus drug therapy, Outcome 1 Number of participants cured.

Review: Electrical stimulation with non-implanted electrodes for overactive bladder in adults

Comparison: 5 Electrical stimulation (ES) versus drug therapy

Outcome: 1 Number of participants cured

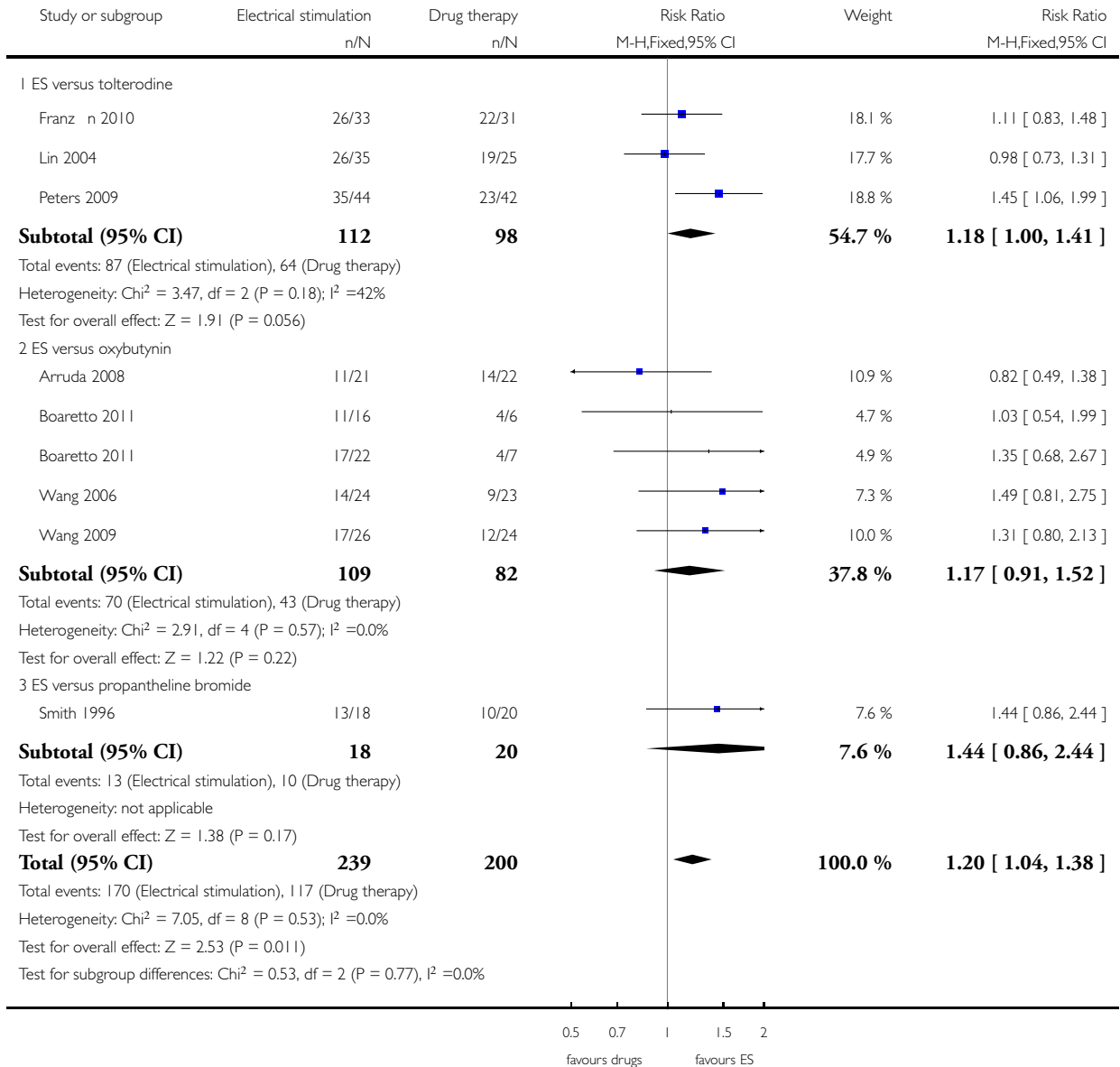


Analysis 5.2. Comparison 5 Electrical stimulation (ES) versus drug therapy, Outcome 2 Number of participants cured or improved.

Review: Electrical stimulation with non-implanted electrodes for overactive bladder in adults

Comparison: 5 Electrical stimulation (ES) versus drug therapy

Outcome: 2 Number of participants cured or improved

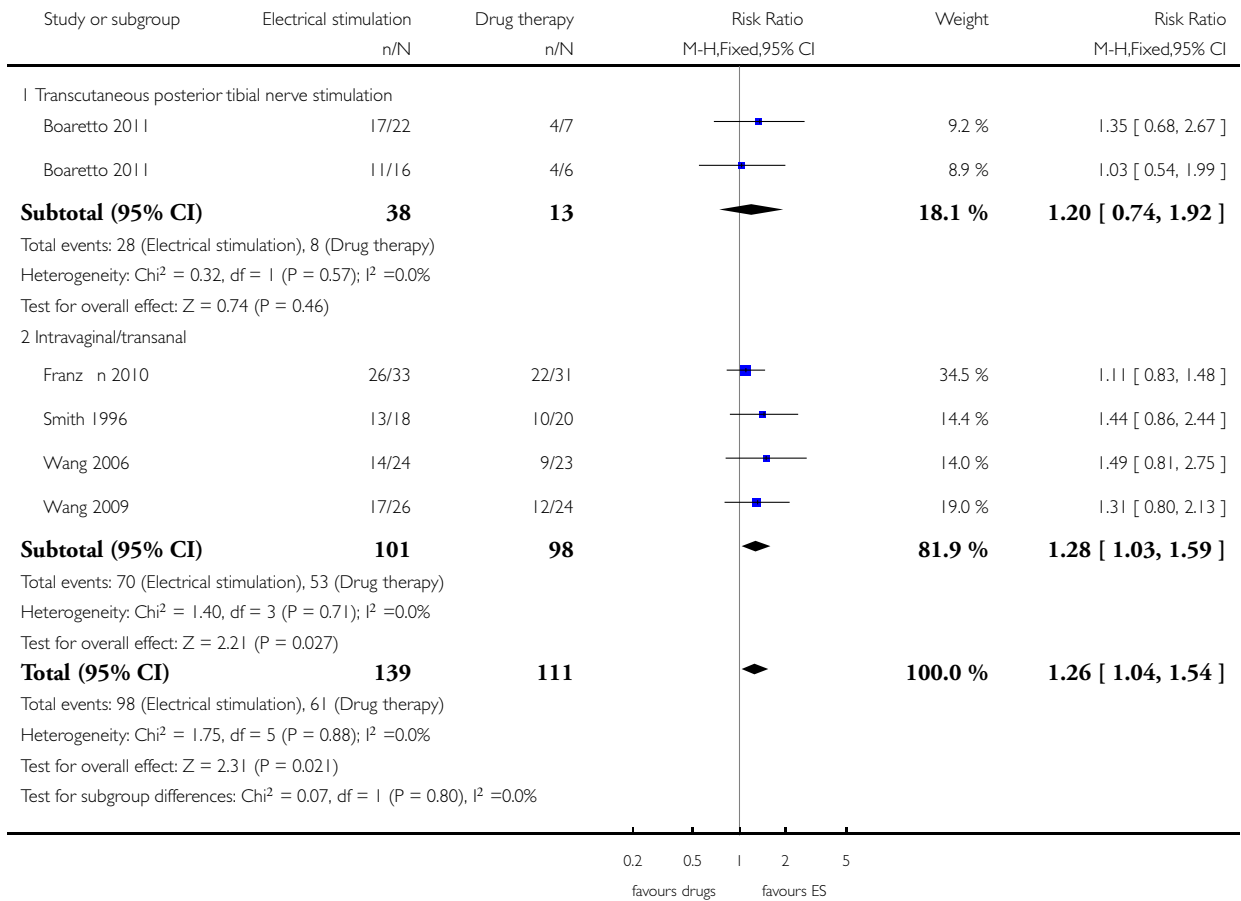


Analysis 5.3. Comparison 5 Electrical stimulation (ES) versus drug therapy, Outcome 3 Number of participants cured or improved: routes of ES.

Review: Electrical stimulation with non-implanted electrodes for overactive bladder in adults

Comparison: 5 Electrical stimulation (ES) versus drug therapy

Outcome: 3 Number of participants cured or improved: routes of ES

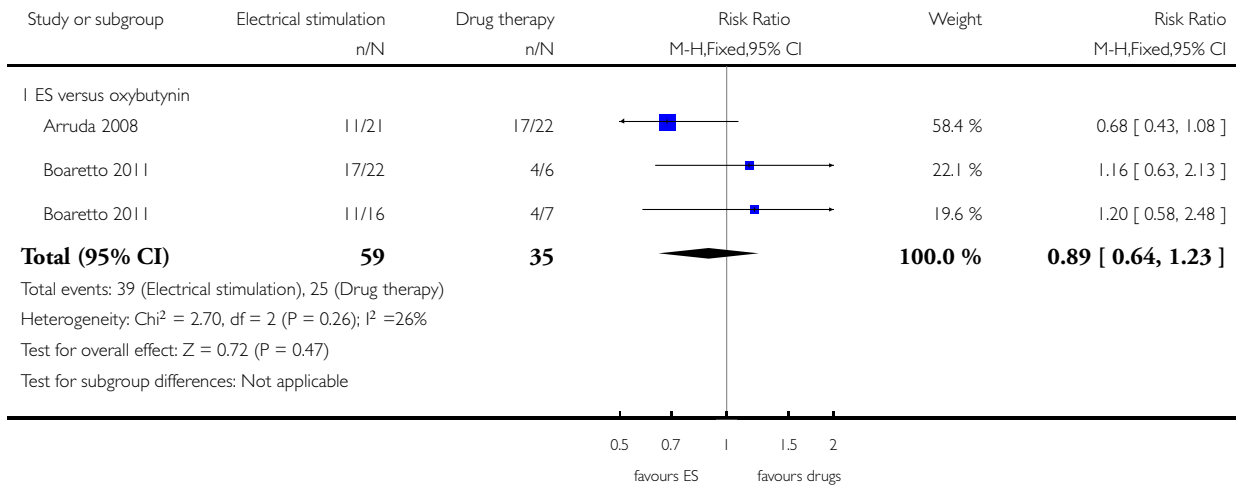


Analysis 5.4. Comparison 5 Electrical stimulation (ES) versus drug therapy, Outcome 4 Number of participants satisfied.

Review: Electrical stimulation with non-implanted electrodes for overactive bladder in adults

Comparison: 5 Electrical stimulation (ES) versus drug therapy

Outcome: 4 Number of participants satisfied

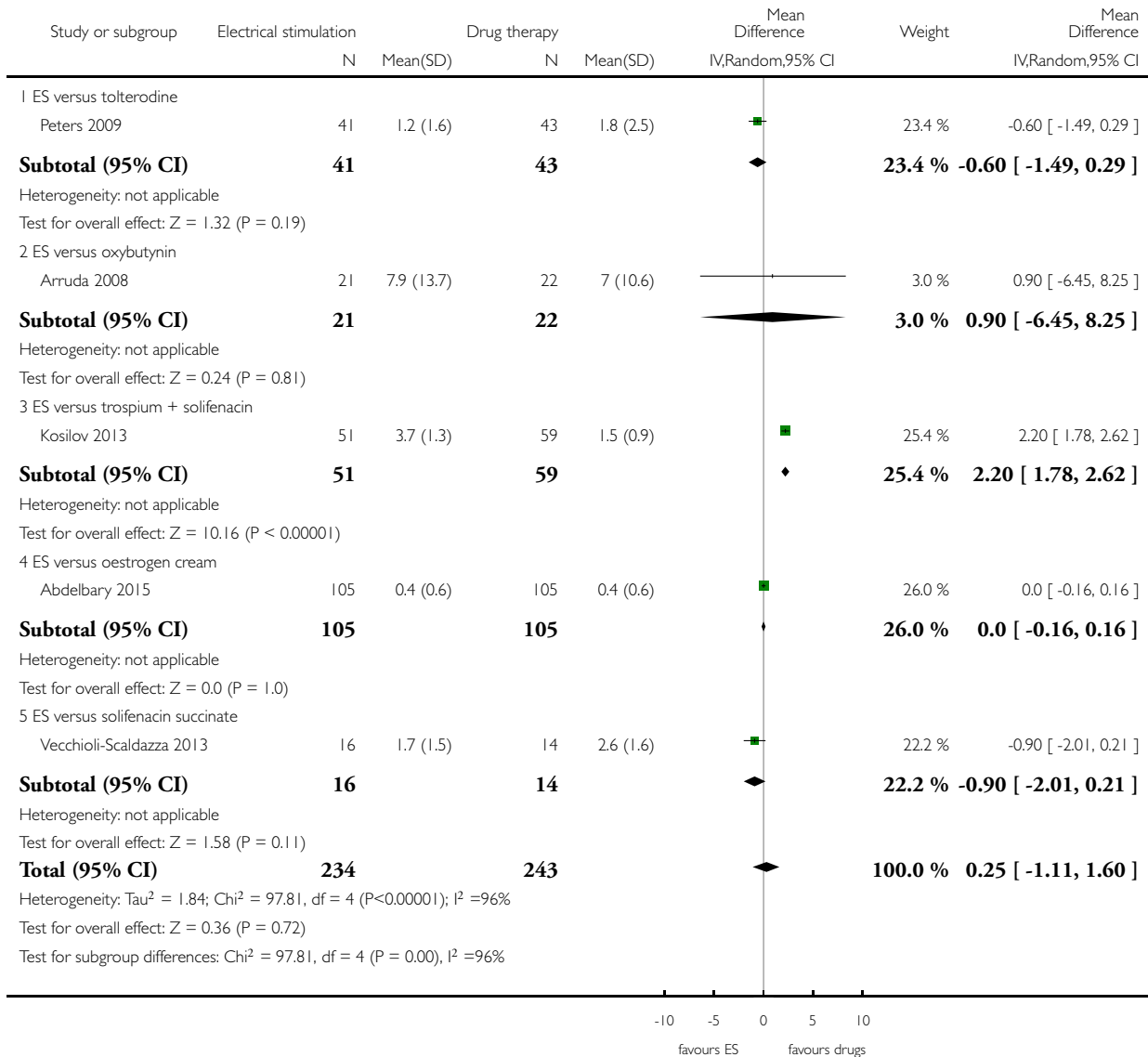


Analysis 5.5. Comparison 5 Electrical stimulation (ES) versus drug therapy, Outcome 5 Number of incontinence episodes per 24 h.

Review: Electrical stimulation with non-implanted electrodes for overactive bladder in adults

Comparison: 5 Electrical stimulation (ES) versus drug therapy

Outcome: 5 Number of incontinence episodes per 24 h

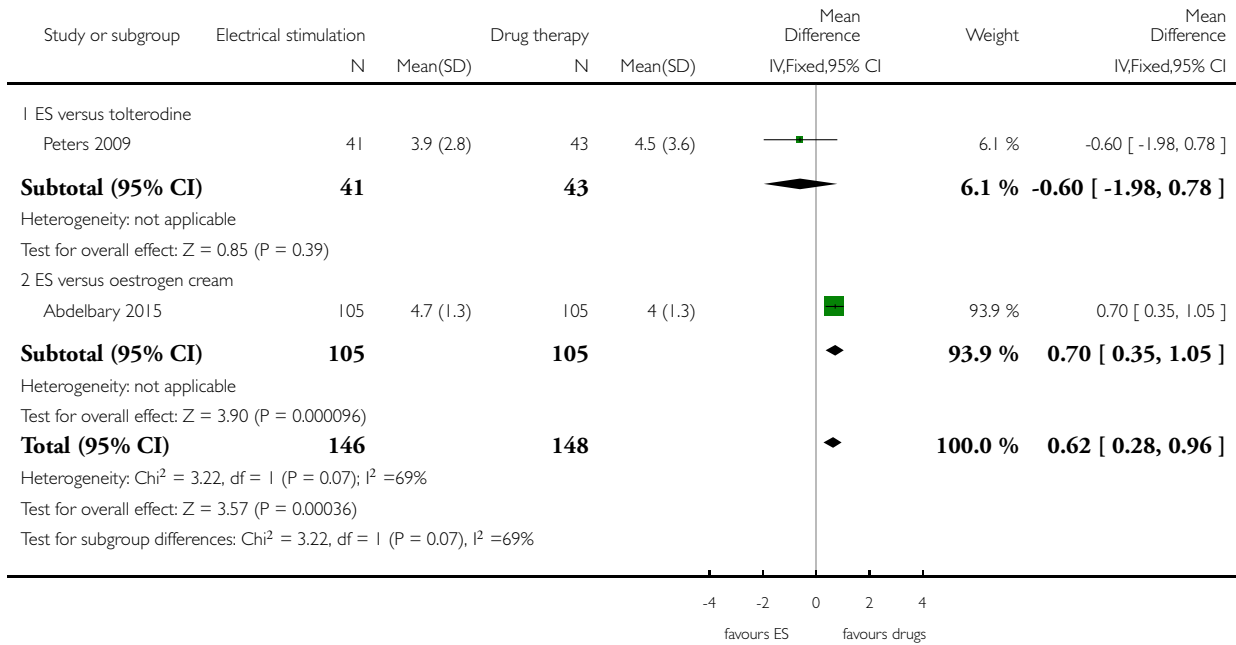


Analysis 5.6. Comparison 5 Electrical stimulation (ES) versus drug therapy, Outcome 6 Number of urgency episodes per 24h.

Review: Electrical stimulation with non-implanted electrodes for overactive bladder in adults

Comparison: 5 Electrical stimulation (ES) versus drug therapy

Outcome: 6 Number of urgency episodes per 24h

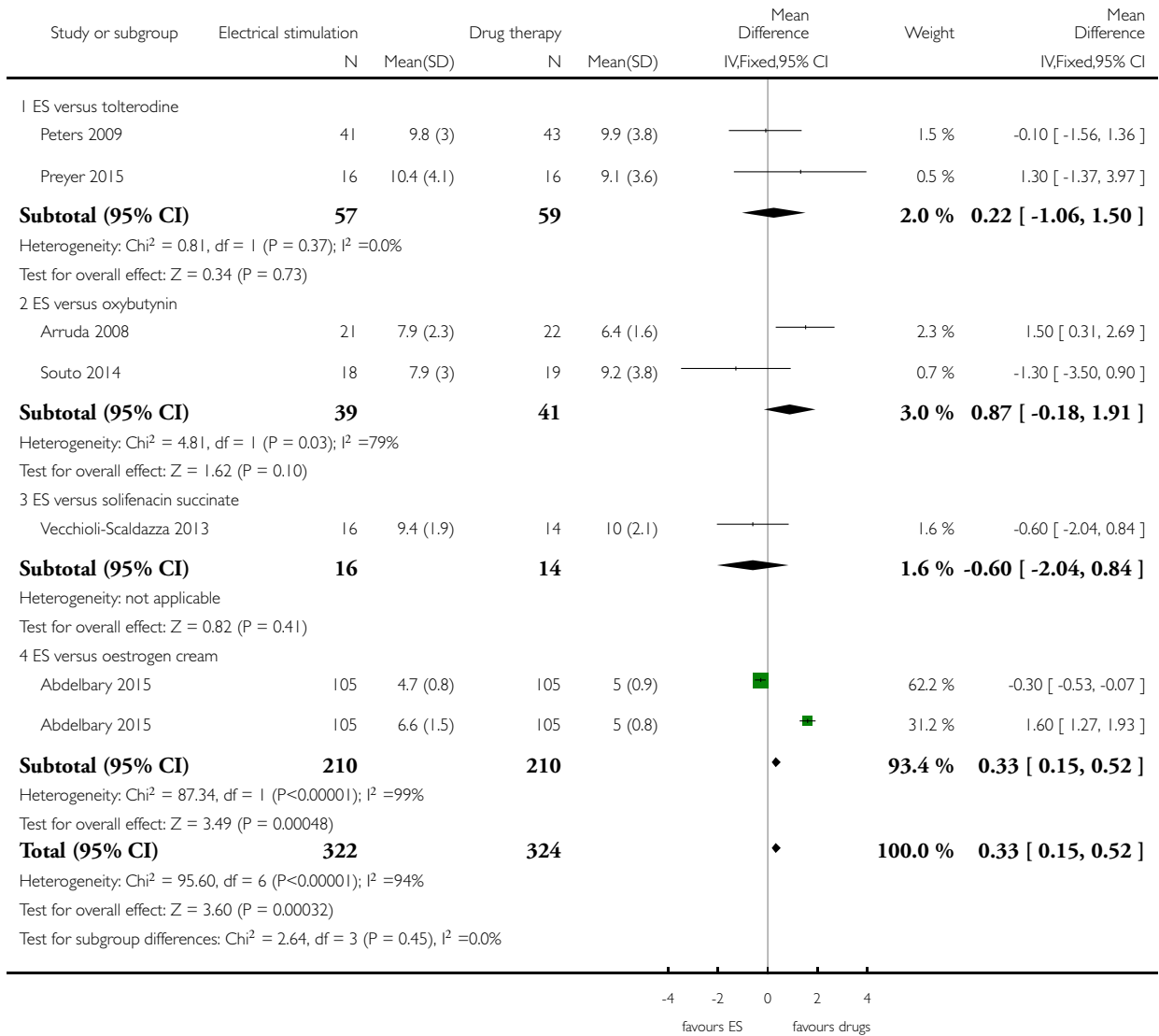


Analysis 5.7. Comparison 5 Electrical stimulation (ES) versus drug therapy, Outcome 7 Number of micturitions per 24 h.

Review: Electrical stimulation with non-implanted electrodes for overactive bladder in adults

Comparison: 5 Electrical stimulation (ES) versus drug therapy

Outcome: 7 Number of micturitions per 24 h

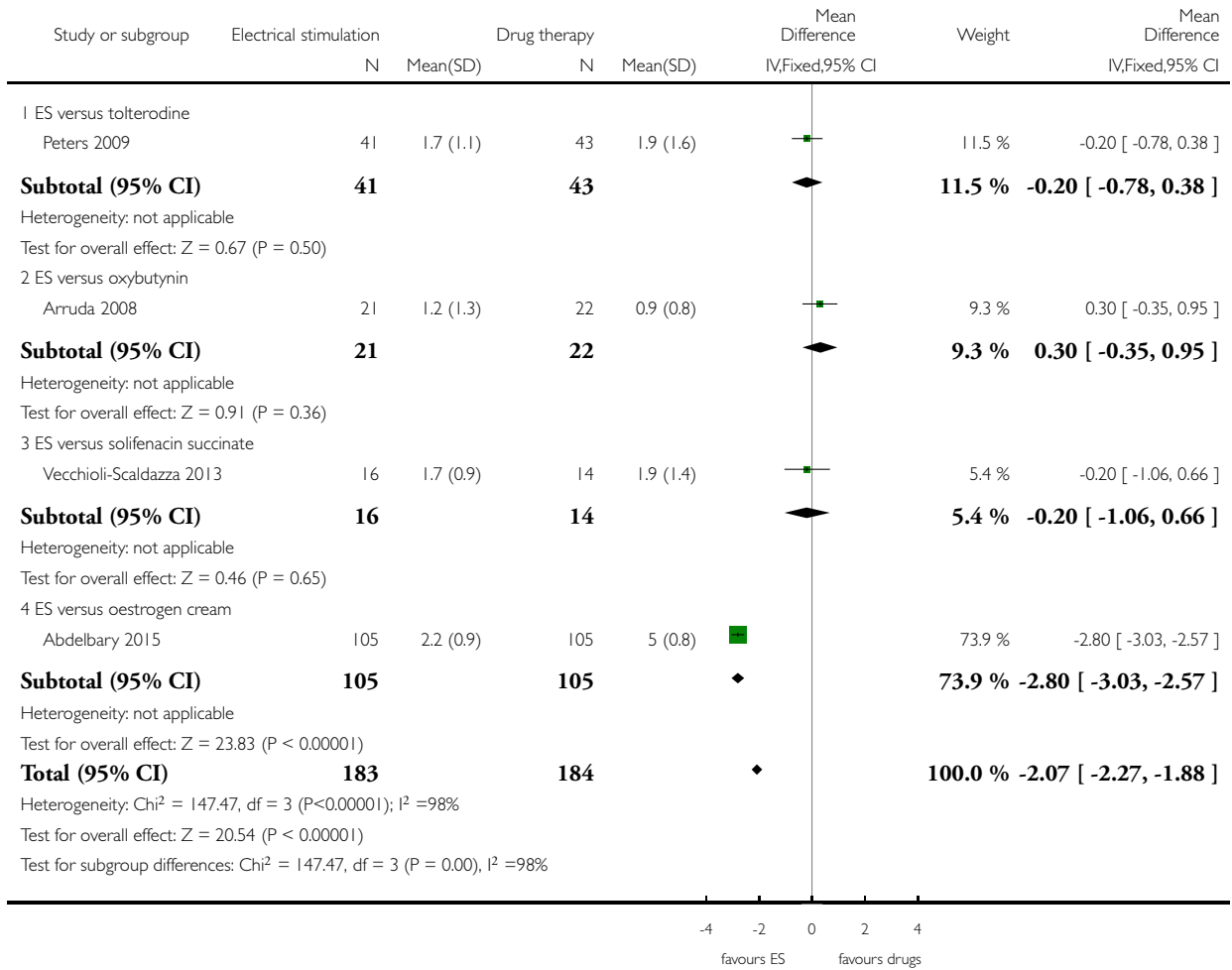


Analysis 5.8. Comparison 5 Electrical stimulation (ES) versus drug therapy, Outcome 8 Number of nocturia episodes per night.

Review: Electrical stimulation with non-implanted electrodes for overactive bladder in adults

Comparison: 5 Electrical stimulation (ES) versus drug therapy

Outcome: 8 Number of nocturia episodes per night

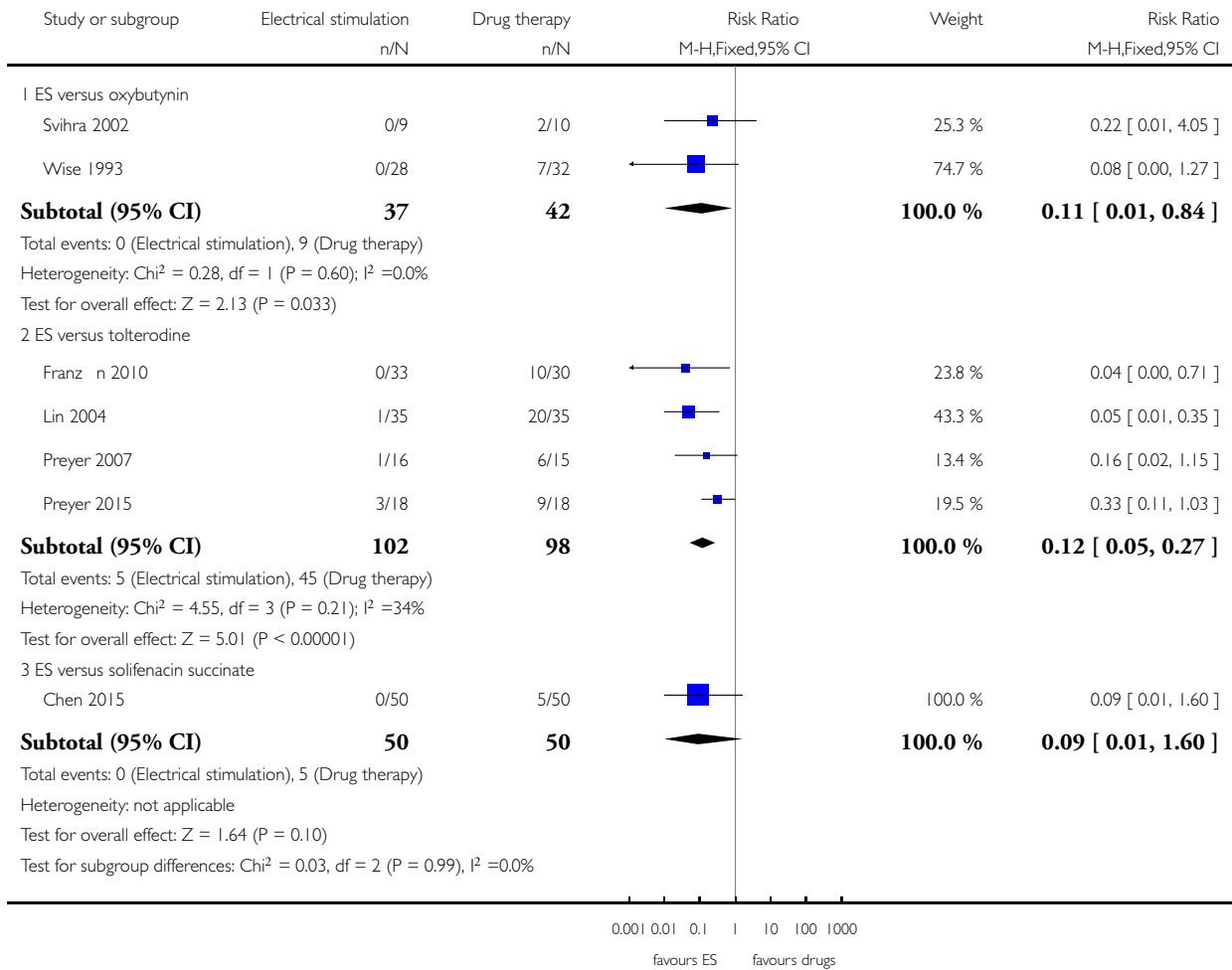


Analysis 5.9. Comparison 5 Electrical stimulation (ES) versus drug therapy, Outcome 9 Number of participants with adverse effects.

Review: Electrical stimulation with non-implanted electrodes for overactive bladder in adults

Comparison: 5 Electrical stimulation (ES) versus drug therapy

Outcome: 9 Number of participants with adverse effects

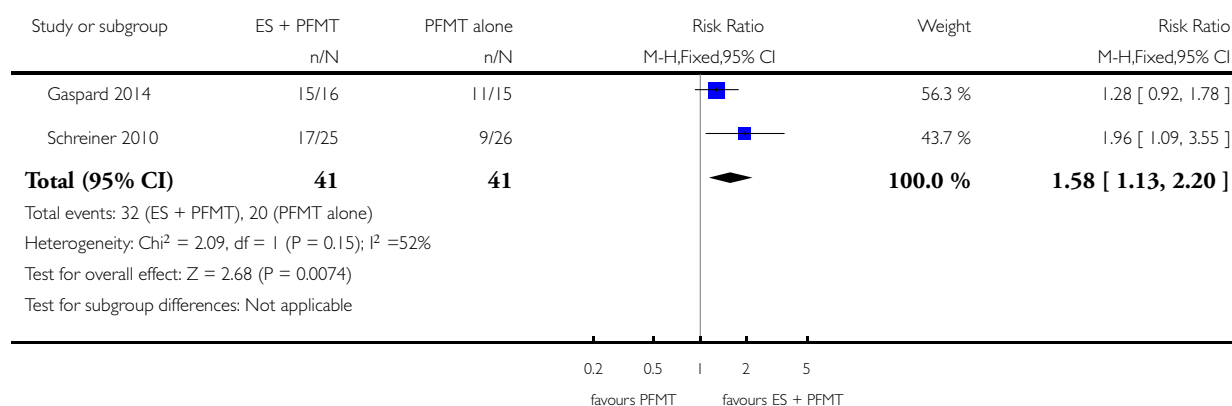


Analysis 6.1. Comparison 6 Electrical stimulation (ES) plus pelvic floor muscle training (PFMT) versus PFMT alone, Outcome 1 Number of participants satisfied.

Review: Electrical stimulation with non-implanted electrodes for overactive bladder in adults

Comparison: 6 Electrical stimulation (ES) plus pelvic floor muscle training (PFMT) versus PFMT alone

Outcome: 1 Number of participants satisfied

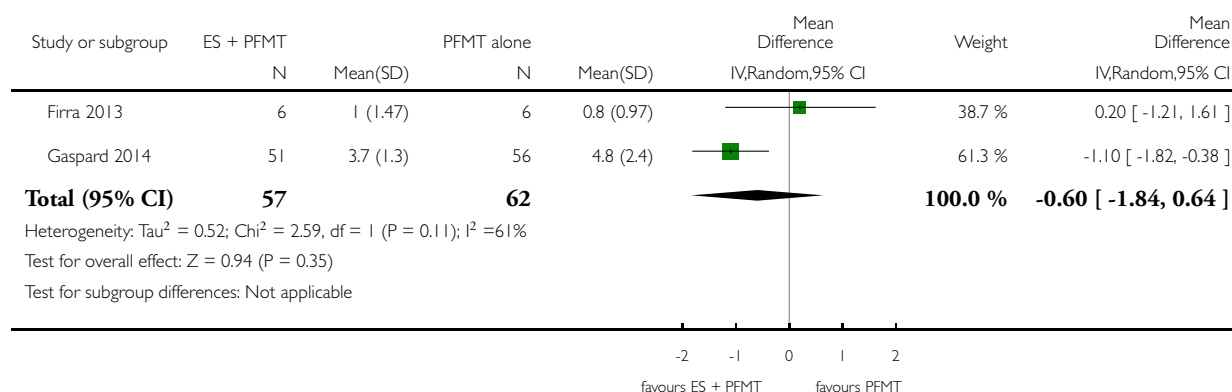


Analysis 6.2. Comparison 6 Electrical stimulation (ES) plus pelvic floor muscle training (PFMT) versus PFMT alone, Outcome 2 Number of incontinence episodes per 24h.

Review: Electrical stimulation with non-implanted electrodes for overactive bladder in adults

Comparison: 6 Electrical stimulation (ES) plus pelvic floor muscle training (PFMT) versus PFMT alone

Outcome: 2 Number of incontinence episodes per 24h

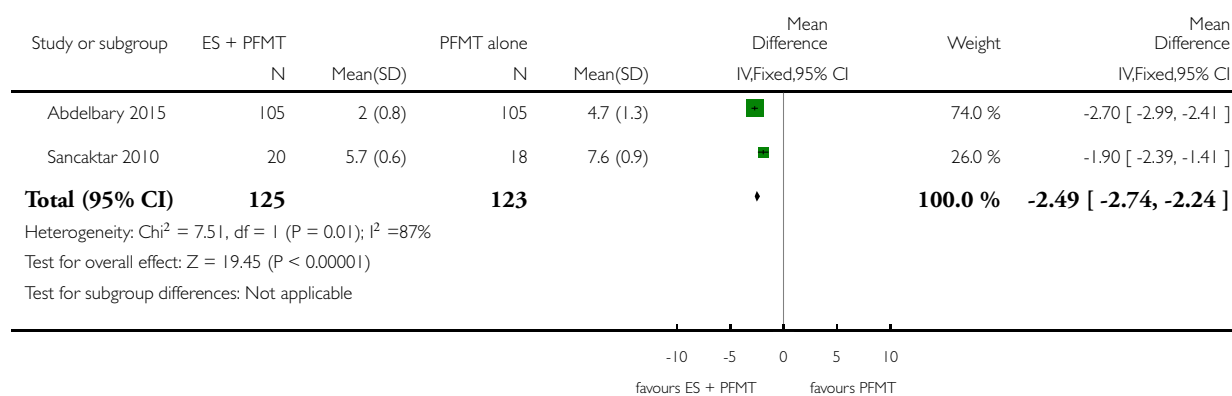


Analysis 6.3. Comparison 6 Electrical stimulation (ES) plus pelvic floor muscle training (PFMT) versus PFMT alone, Outcome 3 Number of urgency episodes per 24 h.

Review: Electrical stimulation with non-implanted electrodes for overactive bladder in adults

Comparison: 6 Electrical stimulation (ES) plus pelvic floor muscle training (PFMT) versus PFMT alone

Outcome: 3 Number of urgency episodes per 24 h

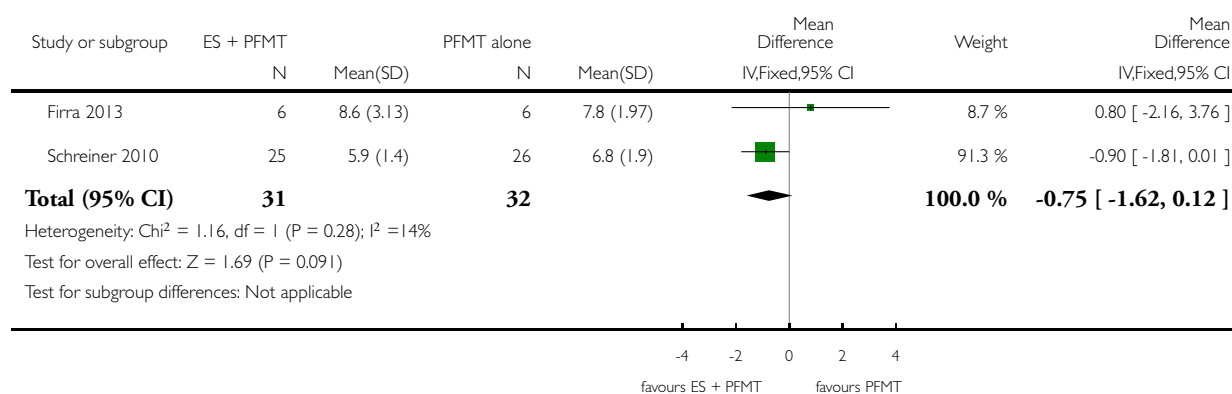


Analysis 6.4. Comparison 6 Electrical stimulation (ES) plus pelvic floor muscle training (PFMT) versus PFMT alone, Outcome 4 Number of micturitions per 24 h.

Review: Electrical stimulation with non-implanted electrodes for overactive bladder in adults

Comparison: 6 Electrical stimulation (ES) plus pelvic floor muscle training (PFMT) versus PFMT alone

Outcome: 4 Number of micturitions per 24 h

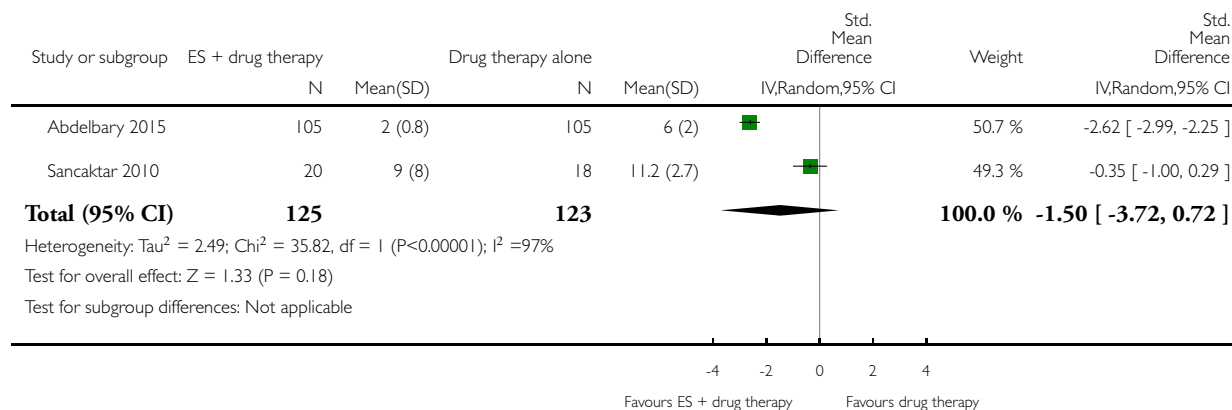


Analysis 7.1. Comparison 7 Electrical stimulation (ES) plus drug therapy versus drug therapy alone, Outcome 1 Quality of life.

Review: Electrical stimulation with non-implanted electrodes for overactive bladder in adults

Comparison: 7 Electrical stimulation (ES) plus drug therapy versus drug therapy alone

Outcome: 1 Quality of life

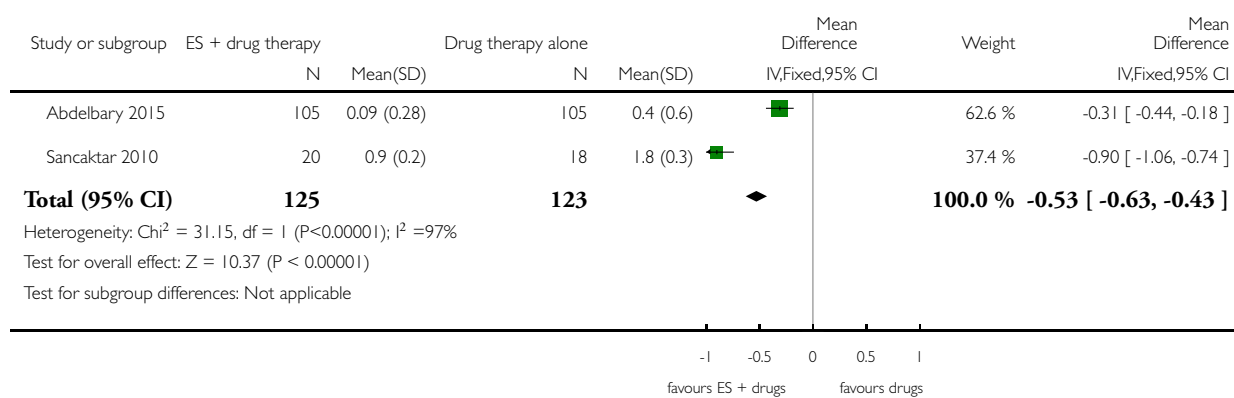


Analysis 7.2. Comparison 7 Electrical stimulation (ES) plus drug therapy versus drug therapy alone, Outcome 2 Number of incontinence episodes per 24h.

Review: Electrical stimulation with non-implanted electrodes for overactive bladder in adults

Comparison: 7 Electrical stimulation (ES) plus drug therapy versus drug therapy alone

Outcome: 2 Number of incontinence episodes per 24h

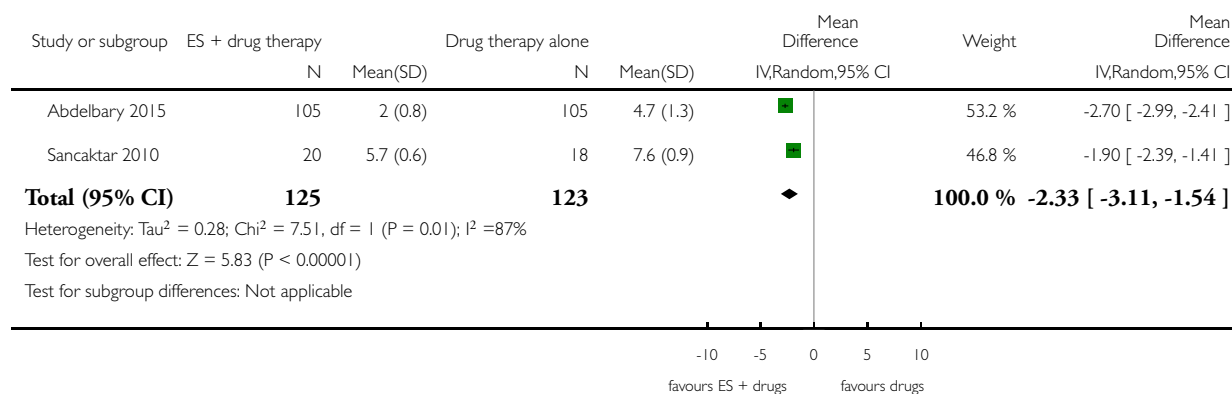


Analysis 7.3. Comparison 7 Electrical stimulation (ES) plus drug therapy versus drug therapy alone, Outcome 3 Number of urgency episodes per 24 hours.

Review: Electrical stimulation with non-implanted electrodes for overactive bladder in adults

Comparison: 7 Electrical stimulation (ES) plus drug therapy versus drug therapy alone

Outcome: 3 Number of urgency episodes per 24 hours

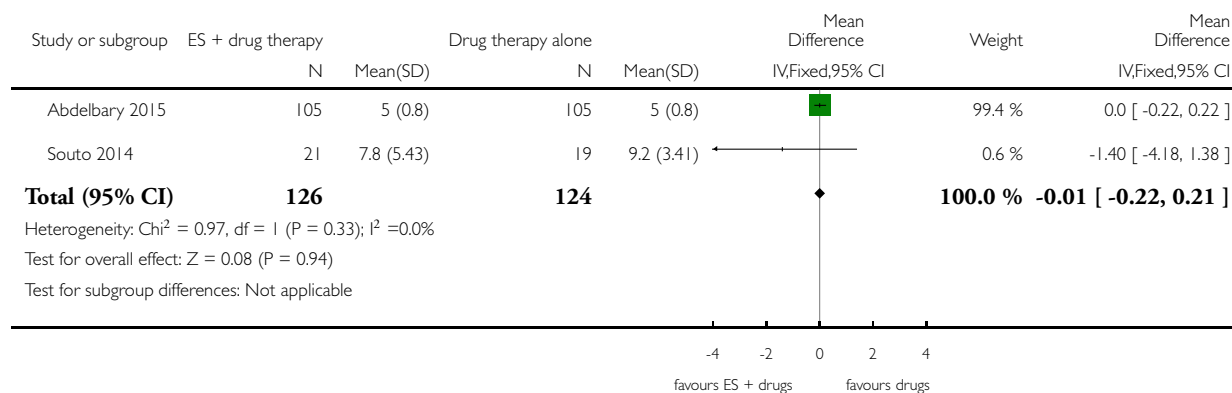


Analysis 7.4. Comparison 7 Electrical stimulation (ES) plus drug therapy versus drug therapy alone, Outcome 4 Number of micturitions per 24 hours.

Review: Electrical stimulation with non-implanted electrodes for overactive bladder in adults

Comparison: 7 Electrical stimulation (ES) plus drug therapy versus drug therapy alone

Outcome: 4 Number of micturitions per 24 hours



ADDITIONAL TABLES

Table 1. Description of electrical stimulation interventions

Study	Current	Current intensity	Pulse shape & duration	Frequency (Hz)	Duty cycle	Electrodes	Treatment duration/supervision
Aaronson 1995	Unclear	Unclear	Unclear	Unclear	Unclear	Intravaginal	Unclear
Abdelbary 2015		30-60 mA according to patient tolerance (mean 43 mA)	320 ms	20	Unclear	Intravaginal	Two 30-min sessions per week for 12 weeks
Alves 2015	Unclear	“Sensory threshold, activating superficial cutaneous nerve fibers with larger diameter”	200 μ s	10	Unclear	Posterior tibial nerve stimulation	Two 30-min sessions per week for 12 weeks
Alves 2015	Unclear	“Motor threshold, non-painful contraction is induced and the stimulation can simply make pain relief in the same way that sensory stimulation level (blocking activation of the peripheral or central inhibition)”	200 μ s	10	Unclear	Posterior tibial nerve stimulation	Two 30-min sessions per week for 12 weeks
Amaro 2006	Bipolar	0-100 mA according to participant tolerance	2 s on, 4 s off	Intravaginal	Three 20-min sessions per week on alter-		

Table 1. Description of electrical stimulation interventions (Continued)

							nate days for 7 weeks
Arruda 2008	Biphasic	10-100 mA according to participant tolerance	1 ms intermittent	10	Unclear	Intravaginal	Two 20-min sessions per week for 12 weeks
Barroso 2002	Biphasic	0-100 mA	Asymmetric, 1 s rise time, sustained for 5 s and resting for 5 s	20	1 s rise time, sustained for 5s and resting for 5 s	Intravaginal	Home use: two 20-min sessions per day for 12 weeks
Bellette 2009	Unclear	Unclear	Unclear	Unclear	Unclear	Transcutaneous posterior tibial nerve	Two 30-min sessions per week for 4 weeks
Berghmans 2002	Biphasic	0-100 mA	Rectangular 200 μ s stochastic variation	4-10	Unclear	Intravaginal	Unclear
Boaretto 2011	Unclear	Unclear	200 μ s	10	Unclear	Transcutaneous posterior tibial nerve	Twelve 30-min sessions
Boaretto 2011	Unclear	Unclear	500 μ s	10	Unclear	Intravaginal	Twelve 30-min sessions
Booth 2013	Unclear	0-50 mA	200 μ s	10	Unclear	Per-cutaneous tibial nerve stimulation	Two 30-min sessions per week for 6 weeks
Bower 1998	Unclear	Unclear	200 μ s	150	Unclear	Transcutaneous electrical nerve stimulation - suprapubic placement	Unclear
Bower 1998	Unclear	Unclear	200 μ s	10	Unclear	Transcutaneous electrical nerve stimulation - sacral placement	Unclear

Table 1. Description of electrical stimulation interventions (Continued)

Brubaker 1997	Bipolar	0-100 mA	Bipolar square wave 0.1 μ s	20	2 s on - 4 s off	Intravaginal	20 minutes daily for 8 weeks
Olmo Carmona 2013	Unclear	0-10 mA	Square wave 320 μ s	20	unclear	Percutaneous posterior tibial nerve stimulation	30 min once a week for 12 weeks
Chen 2015	Bipolar	According to participant tolerance	Continuous bipolar square wave 200 μ s	20	Unclear	Percutaneous posterior tibial nerve stimulation - adhesive skin electrodes	Unclear
Eftekhari 2014	Unclear	Unclear	Unclear	Unclear	Unclear	Transcutaneous posterior tibial nerve stimulation - "34 gauge needle placed 5 cm near internal malleolus"	30-min sessions
Finazzi-Agrò 2010	Unclear	0-10 mA, according to participant tolerance	200 μ s	20	Unclear	Per-cutaneous tibial nerve stimulation	Three 30-min sessions per week for 4 weeks
Firra 2013	Unclear	Unclear current, intensity according to participant tolerance	Unclear	12.5	5 s on, 10 s off	Intravaginal	Fourteen 30-min sessions
Franzén 2010	Unclear	According to participant tolerance	Unclear	5-10		Intravaginal/transanal	10 sessions: 1-2 20-min sessions per week for 5-7 weeks
Gaspard 2014	Biphasic	Unclear	Biphasic rectangular 220 μ s	10	20 s on, 4 s off	Transcutaneous posterior tibial nerve stimulation: external electrode 5 cm above me-	One 30-min session per week for 9 weeks

Table 1. Description of electrical stimulation interventions (Continued)

						dial malleolus, 1 cm behind the tibia. The other electrode on dorsum of foot	
Gonzalez 2015	Unclear	Unclear	Unclear	Unclear	Unclear	Transcutaneous posterior tibial nerve stimulation	Twice a week for 6 weeks, performed by either physiotherapist or continence midwife
Kennelly 2011	Unclear	Unclear	Unclear	Unclear	Unclear	VERV electrode patches, placed by the participant - exact placement unclear	One patch per week for 12 weeks
Kosilov 2013	Diadynamic	20-40 mA, 50%-75% intensity	Unclear	20	Unclear	Active electrode (50 cm ² to 70 cm ²) above the pubis, and a passive electrode (150 cm ²) in lumbosacral area	15 procedures every other day
Lima 2011	Unclear	Unclear	Unclear	Unclear	Unclear	Intravaginal	Twelve 30-min sessions
Lima 2011	Unclear	Unclear	Unclear	Unclear	Unclear	Transcutaneous posterior tibial nerve stimulation	Twelve 30-min sessions
Lin 2004	Unclear	8-70 mA	Unclear	Unclear	Unclear	Vaginal/anorectal	20-30 20-min sessions
Lo 2003	Unclear	According to participant tolerance	Unclear	0-100	Unclear	Interferential therapy. 2 anterior flat electrodes placed over	12 sessions: first session 15 min, all others 30 min

Table 1. Description of electrical stimulation interventions (Continued)

						obturator foramen 1.5 cm to 2 cm lateral to symphysis, two posterior electrodes placed medial to ischial tuberosities either side of anus	
Lobel 1998	Unclear	Unclear	Unclear	Unclear	Unclear	Intravaginal/transanal	Once per week
Lobel 1998	Unclear	Unclear	Unclear	Unclear	Unclear	Intravaginal/transanal	Twice per week
Manriquez 2013	Unclear	Unclear	Unclear	Unclear	Unclear	Transcutaneous tibial nerve stimulation	Twice a week with at least 48 hour intervals for 12 weeks
Marques 2008	Biphasic	Immediately below motor threshold	200 μ s	10	Unclear	Transcutaneous electrical nerve stimulation through 1 channel and 2 electrodes	Two 30-min sessions per week for 4 weeks
Monga 2011	Unclear	Unclear	Unclear	Unclear	Unclear	Transdermal amplitude-modulated signal through a patch applied to the skin, controlled by wireless handheld remote control	Patch worn for 4 weeks
Monteiro 2014	Unclear	Below the threshold that causes motor contraction	200 μ s	10	Unclear	Posterior tibial nerve stimulation with surface electrodes. Negative electrode on me-	30-min twice weekly over 12 sessions (45 days)

Table 1. Description of electrical stimulation interventions (Continued)

						dial malleolus, and the positive electrode 10 cm above negative electrode, also on the medial side. Rhythmic flexion of the second toe during the stimulation determined the correct position of the negative electrode	
Oldham 2013	Unclear	Pre-programmed to increase intensity over 24 s to reach therapeutic level and switch off automatically after 30 min. All devices same level of stimulation (average intensity considered comfortable and capable of producing contractions of pelvic floor muscles)	Unclear	During the 10 s "on time" the device delivers 10 repeats of a short high intensity burst of 50 Hz stimulation immediately preceded by a doublet (125 Hz), superimposed on continuous low frequency 2 Hz stimulation	10 s on, 10 s off	Intravaginal, single-use tampon-like Pelviva device	One disposable device per day for 12 weeks except during menstruation
Orhan 2015	Unclear	Unclear	Unclear	Unclear	Unclear	Percutaneous posterior tibial nerve stimulation	Unclear
Peters 2009	Unclear	Unclear	Unclear	Unclear	Unclear	Percutaneous tibial nerve stimulation: 34-gauge	One 30-min session per week for 12 weeks

Table 1. Description of electrical stimulation interventions (Continued)

						needle slightly cephalad to medial malleolus	
Peters 2010	Unclear	0.5-9 mA	Unclear	20	Unclear	Per-cutaneous tibial nerve stimulation: 34-gauge needle inserted at 60° angle 5 cm cephalad to medial malleolus, slightly posterior to tibia. Surface electrode placed on ipsilateral calcaneus	One 30-min session per week for 12 weeks
Phillips 2012	Unclear	Unclear	Unclear	Unclear	Unclear	Participant-managed neuromodulation system patch	Subject placement versus investigator placement
Preyer 2007	Unclear	Unclear	Unclear	Unclear	Unclear	Peripheral tibial neurostimulation	One 30-min session per week for 12 weeks
Preyer 2015	Unclear	Unclear	Unclear	Unclear	Unclear	Percutaneous posterior tibial nerve stimulation	One 30-min session per week for 3 months
Sancaktar 2010	Unclear	0.5-10 mA, according to participant tolerance	200 µs	20	Unclear	Stoller afferent neurostimulation: 34-gauge needle inserted at 30° angle 2 cm to 3 cm superior-medial aspect of tibial medial malleolus along posterior tibial nerve trace	One 30-min session per week for 12 weeks

Table 1. Description of electrical stimulation interventions (Continued)

Schmidt 2009	Biphasic	Controlled by participant according to tolerance	300 μ s	Asymmetrical, 50	Unclear	Intravaginal: probe with two 26 mm rings 40 mm apart	Unclear
Schreiner 2010	Unclear	Unclear	200 μ s	10	Unclear	Transcutaneous tibial nerve stimulation	One 30 min session per week for 12 weeks
Schreiner 2014	Unclear	Unclear	Unclear	Unclear	Unclear	Transcutaneous posterior tibial nerve stimulation	Unclear
Seth 2014	Unclear	Unclear	Unclear	Unclear	Unclear	Transcutaneous: discrete [sic], self-contained, portable device adhesive to the skin	One 30 min session per day for 12 weeks
Seth 2014	Unclear	Unclear	Unclear	Unclear	Unclear	Transcutaneous: discrete [sic], self-contained, portable device adhesive to the skin	One 30-min session per week for 12 weeks
Shepherd 1984	Unclear	Up to 40 v	Unclear	10-50	Unclear	Maximum perineal stimulation: Scott electrode in vagina, large indifferent electrode under buttocks	Single 20-min session
Shepherd 1985	Unclear	Unclear	Unclear	10	Unclear	Intravaginal cushion attached to stimulator worn around waist	Cushion worn for 8 out of 24 h, day or night according to participant preference

Table 1. Description of electrical stimulation interventions (Continued)

Slovak 2015	Unclear	Stimulus intensity just below that which would cause a motor contraction of toes/shoulder muscles	Unclear	Unclear	Unclear	Unilateral posterior tibial nerve stimulation with conventional TENS machine - electrodes placed above and below the medial malleolus on the right ankle	Unclear
Slovak 2015	Unclear	Stimulus intensity just below that which would cause a motor contraction of toes/shoulder muscles	Unclear	Unclear	Unclear	Bilateral posterior tibial nerve stimulation with conventional TENS machine - electrodes placed above and below the medial malleolus on both ankles	Unclear
Smith 1996	Unclear	5-25 mA	Unclear	Device uses 2 programmes simultaneously: 12.5 Hz and 50 Hz	5 s impulse	Intravaginal	Twice daily for 4 months. Length of session increased monthly: 15, 30, 45, 60 minutes
Soomro 2001	Unclear	Participants asked to control stimulation to achieve tickling sensation	200 μ s	20	Continuous	Transcutaneous. 2 self-adhesive pads applied bilaterally over the perianal region (S2-S3 dermatome)	Up to 6 hours daily for 6 weeks
Sotelo 2011	Unclear	Unclear	Unclear	Unclear	Unclear	Transdermal. Carrier signal and pulse envelope through	Patch worn continuously for 7 days

Table 1. Description of electrical stimulation interventions (Continued)

						patch applied on skin over spinal nerves in lower back Horizontal placement of electrode patch near sacral nerve	
Sotelo 2011	Unclear	Unclear	Unclear	Unclear	Unclear	Transdermal. Carrier signal and pulse envelope through patch applied on skin over spinal nerves in lower back 30° angle placement of electrode patch near sacral nerve	Patch worn continuously for 7 days
Souto 2014	Unclear	According to participant tolerance	250 µs	10	Unclear	Posterior tibial nerve stimulation. Surface electrode placed behind media malleolus and another placed 10 cm above first electrode	Two 30 min sessions per week for 12 weeks
Spruijt 2003	Biphasic	0-100 mA, according to participant tolerance	100 µs	20	2 s contraction time, duty cycle 1-2 s	Intravaginal	Three 30-min sessions per week for 8 weeks. 5 min rest between each 15 min
Svihra 2002	Square	25 mA. 70% of intensity of maximal amplitude of registered response from	Square impulse 100 µs	1	Unclear	Stoller afferent neurostimulation. Electrodes placed behind medial	One 30 min session per week for 5 weeks

Table 1. Description of electrical stimulation interventions (Continued)

		abductor hal- lucis muscle				ankle of left lower extrem- ity, cathode placed proxi- mally and an- ode distally	
Vahtera 1997	Unclear	Accord- ing to partici- pant tolerance	Unclear	10 min of each frequency, 3 min: 5-10 Hz, 10-50 Hz, 50 Hz	7 s on, 25 s off	Intravaginal/ transanal	6 sessions over two weeks
Vecchioli- Scaldazza 2013	Unclear	Unclear	Unclear	Unclear	Unclear	Per- cutaneous tib- ial nerve stimu- lation	Two 30-min sessions per week for 6 weeks
Vohra 2002	Unclear	0-10 mA	Unclear	Unclear	Unclear	Percutaneous posterior tibial nerve stimula- tion	One 30-min ses- sion per week for 12 weeks
Walsh 2001	Unclear	Unclear	200 ms	10	Unclear	Transcuta- neous neu- rostimulation. Electrode pads affixed bilater- ally to the skin overlying S3 dermatomes (junction of buttock and upper thigh)	Single session
Wang 2004	Biphasic	Minimum 20- 63 mA, maxi- mum 40-72 mA, ac- cording to par- ticipant toler- ance	Biphasic sym- metrical 400 μ s	10	10 s on, 5 s off	Intravaginal	Two 20-min ses- sions per week for 12 weeks
Wang 2006	Biphasic	Minimum 20- 63 mA, maxi- mum 40-72 mA, ac- cording to par- ticipant toler- ance	Biphasic sym- metrical 400 μ s	10	10 s on, 5 s off	Intravaginal	Two 20-min ses- sions per week for 12 weeks

Table 1. Description of electrical stimulation interventions (Continued)

Wang 2009	Biphasic	Minimum 20-63 mA, maximum 40-72 mA, according to participant tolerance	Biphasic symmetrical 400 μ s	10	10 s on, 5 s off	Intravaginal	Two 20-min sessions per week for 12 weeks
Wise 1992	Unclear	Unclear	Unclear	Unclear	Unclear	Intravaginal	One session per day (at home) for 6 weeks
Wise 1993	Unclear	0-90 mA, according to participant tolerance	Unclear	20	Unclear	Intravaginal	One session per day (at home) for 6 weeks
Yamanishi 2000	Square	0-60 mA, according to participant tolerance	Square, 1 ms	10	Unclear	Intravaginal (women), surface electrode or anal plug (men) Surface electrode placed on dorsal part of penis. Anal electrode bullet-shaped, vaginal plug cylindrical-formed with ring-formed electrodes	Two 15-min sessions per day for 4 weeks
Yamanishi 2000	Square	0-60 mA, according to participant tolerance	Square, 1 ms	10	Unclear	Intravaginal (women), surface electrode or anal plug (men) Surface electrode placed on dorsal part of penis. Anal electrode bullet-shaped, vagi-	Single session

Table 1. Description of electrical stimulation interventions (Continued)

							nal plug cylinder-formed with ring-formed electrodes	
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Table 2. Electrical stimulation (ES) versus no active treatment

Study	Outcome	ES (mean (SD)/range), N or n/N; if available)	No active treatment (mean (SD), N or n/N; if available)	Result
Primary outcomes: cure/improvement of OAB symptoms; OAB-related quality of life				Primary outcome of life
Svihra 2002	Improvement in QoL measured by Incontinence Quality of Life Questionnaire, Behavioural Urge Score and International Prostate Symptom Score	5/9	0/9	RR 11.00 (95% CI 0.70 to 173.66)
Oldham 2013	ICI-Q score ¹	Median (range), N: 6 (0-17), 64	Median (range), N: 9 (3-18), 60	Not estimable
Secondary outcomes				Secondary outcome
Marques 2008	Daytime frequency	NR	NR	Favours ES P = 0.0001
	Nocturia	NR	NR	Favours ES P = 0.0186
Monteiro 2014	Participants with nocturnal enuresis	45 days' treatment: 0/12	45 days' treatment: 2/12	Favours ES RR 5.00 (95% CI 1.63 to 15.31)
		12 months' follow-up: 0/12	12 months' follow-up: 2/12	
	Participants with nocturia	45 days' treatment: 5/12	45 days' treatment: 9/12	RR 2.33 (95% CI 0.78 to 6.94)
12 months' follow-up: 1/12		12 months' follow-up: 6/12	Favours ES RR 0.17 (95% CI 0.02 to 1.18)	
	Participants with increased daytime frequency	45 days' treatment: 3/12	45 days' treatment: 11/12	Favours ES RR 0.27 (95% CI 0.10 to 0.74)

Table 2. Electrical stimulation (ES) versus no active treatment (Continued)

		12 months' follow-up: 0/12	12 months' follow-up: 9/12	Favours ES RR 0.05 (95% CI 0.00 to 0.81)
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Results in bold are statistically significant

¹Higher score = greater severity

Table 3. Electrical stimulation (ES) versus placebo/sham treatment

Study	Outcome	ES (mean (SD)/range), N or n/N; if available)	Placebo or sham treatment (mean (SD), N or n/N; if available)	Result	
Primary outcomes: cure/improvement of OAB symptoms; OAB-related quality of life					Primary outcome: quality of life
Booth 2013	ICIQ-SF score	Median (IQR), N: 2 (0 to -6), 15	0 (-3 to 3), 13	P = 0.132	
	Participants with improvement in ICIQ-SF score	10/15	6/13	RR 1.44 (95% CI 0.73 to 2.87)	
Belletto 2009	OAB-Q total score ¹	83.99 (16.99), 21	66.63 (25.06), 16	Favours ES MD 17.36 (95% CI 3.09 to 31.63)	
Finazzi-Agrò 2010	I-QoL score ¹	69.9 (65.8-73.3), 17	70.6 (62.2-79.1), 15	No evidence of a difference	
Kennelly 2011	Change in OAB-Q score	Median (IQR), N: 8.8 (1.6 to 20.0), 80	Median (IQR), N: 9.2 (-0.8 to 27.2), 83	P = 0.9918	
Peters 2010	Change in OAB-Q score	36.7 (21.5), 101	29.2 (20.0), 102	Favours ES MD 7.50 (1.79, 13.21)	
Yamanishi 2000a	QoL score ²	1.6 (0.7), 37	2.2 (0.9), 31	Favours ES MD -0.60 (95% CI -0.99 to -0.21)	
Secondary outcomes: clinicians' observations and other quantification of symptoms					Secondary outcome: symptoms
Yamanishi 2000a	Number of pads per day	0.8 (1.2), 37	1.1 (2.0), 31	MD -0.30 (95% CI -1.10 to 0.50)	

Table 3. Electrical stimulation (ES) versus placebo/sham treatment (Continued)

Other outcomes				Other outcomes
Amaro 2006	Participants with reduction in analogue discomfort sensation	8/20	5/20	RR 1.60 (95% CI 0.63 to 4.05)
	Participants with reduction in analogue wetness sensation	6/20	5/20	RR 1.20 (95% CI 0.44 to 3.30)
	Pelvic floor muscle strength (cmH ₂ O)	53.8 (18.6), 20	46.8 (12.5), 20	MD 7.00 (95% CI -2.82 to 16.82)
Yamanishi 2000a	Urgency score ²	1.7 (0.7), 37	sham ES: 2 (0.8), 31	MD -0.30 (95% CI -0.66 to 0.06)

Results in bold are statistically significant

¹Lower score = greater severity

²Higher score = greater severity

Table 4. Electrical stimulation (ES) versus pelvic floor muscle training (PFMT)

Study	Outcome	ES (mean (SD)/range), N or n/N; if available)	PFMT (mean (SD), N or n/N; if available)	Result
Primary outcomes: cure/improvement of OAB symptoms; OAB-related quality of life				Primary outcomes: quality of life
Arruda 2008	Participants cured	14/21	12/21	RR 1.17 (95% CI 0.72 to 1.88)
Wang 2004	Participants with improvement in UII	9/18	13/34	RR 1.62 (95% CI 0.51 to 5.12)
	King's Health Questionnaire score ¹	180.08 (176.03), 35	50.27 (171.42), 34	Favours ES MD 129.81 (95% CI 47.83 to 211.79)
Secondary outcomes: clinicians' observations and other quantification of symptoms				Secondary outcomes: symptoms
Arruda 2008	Incontinence episodes per 24 hours	7.9 (13.7), 21	7.8 (15.3), 21	MD 0.10 (95% CI -8.68 to 8.88)
	Micturitions per 24 hours	7.9 (2.3), 21	71. (2.1), 21	MD 0.80 (95% CI -0.53 to 2.13)

Table 4. Electrical stimulation (ES) versus pelvic floor muscle training (PFMT) (Continued)

	Nocturia episodes per night	1.2 (1.3), 21	1 (1.1), 21	MD 0.20 (95% CI -0.53 to 0.93)
	Number of pads per day	0.9 (1.7), 21	0.8 (1.3), 21	MD 0.10 (95% CI -0.82 to 1.02)

¹Higher score = greater QoL

Table 5. Electrical stimulation (ES) versus pelvic floor muscle training (PFMT) plus biofeedback

Study	Outcome	ES (mean (SD)/range), N or n/N; if available)	PFMT plus biofeedback (mean (SD), N or n/N; if available)	Result
Primary outcomes: cure/improvement of OAB symptoms; OAB-related quality of life				Primary outcome quality of life
Wang 2004	Participants with improvement in UII	9/17	17/34	RR 1.06 (95% CI 0.60 to 1.85)
	King's Health Questionnaire score ¹	180.08 (176.03), 35	185.86 (176.57), 34	MD -5.78 (95% CI -88.99 to 77.43)

¹Higher score = greater QoL

Table 6. Electrical stimulation (ES) versus laseropuncture/electro-acupuncture

Study	Outcome	ES (mean (SD)/range), N or n/N; if available)	Laseropuncture/electro-acupuncture (mean (SD), N or n/N; if available)	Result
Primary outcomes: cure/improvement of OAB symptoms; OAB-related quality of life				Primary outcome quality of life
Olmo Carmona 2013	Bladder Self-Assessment Questionnaire score	5.18 (2.56), 11	7.27 (2.24), 11	Favours ES MD -2.09 (95% CI -4.10 to -0.08)
Secondary outcomes: clinicians' observations and other quantification of symptoms				Secondary outcome symptoms
Olmo Carmona 2013	Micturitions per day	8 (1.73), 11	7.73 (1.67), 11	MD 0.27 (95% CI -1.15 to 1.69)

Table 6. Electrical stimulation (ES) versus laserpuncture/electro-acupuncture (Continued)

	Nocturia episodes per night	1.09 (1.51), 11	2.09 (1.92), 11	MD -1.00 (95% CI -2.44 to 0.44)
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¹Higher score = greater severity

Table 7. Electrical stimulation (ES) versus drug therapy

Study	Outcome	ES (mean (SD)/range), N or n/N; if available)	Comparator (mean (SD), N or n/N; if available)	Result
Primary outcomes: cure/improvement of OAB symptoms; OAB-related quality of life				Primary outcome quality of life
Aaronson 1995	Participants cured or improved	69% (N not reported)	Probanthine 50% (N not reported)	Not estimable
Chen 2015	I-QoL score ¹	25.2 (1.0), 50	Solifenacin succinate: 24.2 (1.0), 48	MD 1.00 (95% CI 0.60 to 1.40)
Vecchioli-Scaldazza 2013	OAB-Q score ²	2.9 (0.9), 14	Solifenacin succinate: 3.1 (1.1), 14	MD -0.20 (95% CI -0.94 to 0.54)
	Patient Global Impression of Improvement score ²	2.1 (0.7), 14	Solifenacin succinate: 2.9 (1.1), 14	Favours ES MD -0.80 (95% CI -1.48 to -0.12)
	Participant Perception of Intensity of Urgency Scale score ²	2.1 (0.9), 14	Solifenacin succinate: 2.7 (1.2), 14	MD -0.60 (95% CI -1.39 to 0.19)
Abdelbary 2015		ES	Oestrogen cream	Favours ES MD -2.20 (95% CI -2.71 to -1.69)
	QoL score ² (instrument not reported)	End of treatment: 2.8 (2), 105 3 months: 4 (1.7), 105 6 months: 7.6 (3), 105	End of treatment: 5 (1.8), 105 3 months: 6 (2), 105 6 months: 6 (2), 105	Favours ES MD -2.00 (95% CI -2.50 to -1.50) MD 1.60 [0.91, 2.29]
Secondary outcomes: clinicians' observations and other quantification of symptoms				Secondary outcome symptoms
		ES	Oestrogen cream	

Table 7. Electrical stimulation (ES) versus drug therapy (Continued)

Abdelbary 2015	Voids per 24 hours	End of treatment: 4.7 (0.8), 105 3 months: 5.0 (1.0), 105 6 months: 6.6 (1.5), 105	End of treatment: 5.0 (0.9), 105 3 months: 5.3 (0.9), 105 6 months: 5.0 (0.8), 105	Favours ES MD (-0.30 (95% CI -0.56 to -0.04)) Favours ES MD -0.30 (95% CI -0.53 to -0.07) Favours oestrogen cream MD 1.60 (95% CI 1.27 to 1.93)
	Nocturia episodes per night	End of treatment: 0.9 (0.7), 105 3 months: 1.1 (0.9), 105 6 months: 2.2 (0.9), 105	End of treatment: 1.4 (0.8), 105 3 months: 1.5 (0.8), 105 6 months: 5.0 (0.8), 105	Favours ES MD -0.50 (95% CI -0.70 to -0.30) Favours ES MD -0.40 (95% CI -0.63 to -0.17) MD -2.80 (95% CI -3.03 to -2.57)
	Incontinence episodes	End of treatment: 0.1 (0.3), 105 3 months: 0.1 (0.3), 105 6 months: 0.4 (0.6), 105	End of treatment: 0.4 (0.6), 105 3 months: 0.5 (0.6), 105 6 months: 0.4 (0.6), 105	Favours ES MD -0.30 (95% CI -0.43 to -0.17) Favours ES -0.40 (95% CI -0.53 to -0.27) 0.00 [-0.16, 0.16]
	Urgency episodes	End of treatment: 2 (0.7), 105 3 months: 2.7 (1.0), 105 6 months: 4.7 (1.3), 105	End of treatment: 4 (1.3), 105 3 months: 4.5 (1.5), 105 6 months: 4 (1.3), 105	-3.00 [-3.28, -2.72] -1.80 [-2.14, -1.46] 0.70 [0.35, 1.05]
Arruda 2008	Number of pads per day	0.9 (1.8), 21	Oxybutynin: 0.9 (1.5), 22	MD 0.00 (95% CI -0.96 to 0.96)
Souto 2014	Participants with nocturia	2/18	Oxybutynin: 3/19	RR 0.70 (95% CI 0.13 to 3.73)

Results in bold are statistically significant

¹Lower score = greater severity

²Higher score = greater severity

Table 8. Electrical stimulation (ES) plus pelvic floor muscle training (PFMT) versus PFMT alone

Study	Outcome	ES plus PFMT (mean (SD)/range), N or n/N; if available)	PFMT (mean (SD), N or n/N; if available)	Result
Primary outcomes: cure/improvement of OAB symptoms; OAB-related quality of life				Primary outcome of life
Gaspard 2014	SF-Qualiveen ¹	Median (IQR), N: 9 weeks: 1.000 (0.656, 1.719), 16 6 months: 1.313 (0.687, 1.625), 16.	Median (IQR), N: 9 weeks: 1.375 (0.625, 2.188) 6 months: 1.500 (0.344, 2.094), 15	Not estimable
Firra 2013	York Incontinence Perception Scale ²	41.2 (10.2), 6	47 (5.5), 6	MD -0.65 (95% CI -1.83 to 0.52)
Schreiner 2010	Participants with improvement in UUI	19/25	7/26	Favours ES plus PFMT RR 2.82 (95 CI 1.44 to 5.52)
	ICIQ-SF score ¹	7.9 (4.5), 25	10.6 (4.4), 26	Favours ES plus PFMT MD -2.70 (95% CI -5.14 to -0.26)
Secondary outcomes				Secondary outcome
Schreiner 2010	Nocturia episodes per night	1.3 (1.5), 25	2.4 (1.3), 26	Favours ES plus PFMT MD -1.10 (95% CI -1.87 to -0.33)
	Adverse effects	0/25	0/26	Not estimable
Other outcomes				Other outcome
Firra 2013	Pelvic floor muscle strength (cmH ₂ O)	27 (16), 6	47.2 (22.7), 6	MD -20.20 (95% CI -42.42 to 2.02)

Results in bold are statistically significant

¹Higher score = greater severity

²Higher score = less severity

Table 9. Electrical stimulation (ES) plus behavioural therapy versus behavioural therapy alone

Study	Outcome	ES plus behavioural therapy (mean (SD)/range), N or n/N; if available)	Behavioural therapy (mean (SD), N or n/N; if available)	Result
Primary outcomes: cure/improvement of OAB symptoms; OAB-related quality of life				Primary outcome of life
Gonzalez 2015	OAB-Q score ¹	100.81 (41.5), 31	127.71 (40.64), 37	Favours ES plus behavioural therapy MD -26.90 (95% CI -46.52 to -7.28)
	Incontinence Severity Index score ¹	5.15 (3.23), 31	7.38 (4.00), 37	Favours ES plus behavioural therapy MD -26.90, 95% CI -46.52 to -7.28

Results in bold are statistically significant

¹Higher score = greater severity

Table 10. Electrical stimulation (ES) plus drug therapy versus drug therapy alone

Study	Outcome	ES plus drugs (mean (SD)/range), N or n/N; if available)	Drugs (mean (SD), N or n/N; if available)	Result
Primary outcomes: cure/improvement of OAB symptoms; OAB-related quality of life				Primary outcome of life
Sancaktar 2010	IIQ-7 score ¹	ES plus tolterodine: 9.0 (0.8), 20	Tolterodine: 11.2 (2.7), 18.	Favours ES plus tolterodine MD -2.20 (95% CI -3.50 to -0.90)
Abdelbary 2015		ES plus oestrogen cream:	Oestrogen cream:	
	QoL score ¹ (instrument not reported)	End of treatment: 2.9 (2.2), 105. 3 months: 1.6 (0.9), 105. 6 months: 2 (0.8), 105.	End of treatment: 5 (1.8), 105 3 months: 6 (2), 105 6 months: 6 (2), 105	MD -2.10 (95% CI -2.64, -1.56] MD -4.40 (95% CI -4.82 to -3.98) MD -4.00 (95% CI -4.41 to -3.59)
Secondary outcomes				Secondary outcome
Abdelbary 2015		ES plus oestrogen cream:	Oestrogen cream:	

Table 10. Electrical stimulation (ES) plus drug therapy versus drug therapy alone (Continued)

	Voids per day	End of treatment: 5 (0.8), 105. 3 months: 5 (0.8), 105. 6 months: 5 (0.8), 105.	End of treatment: 5.0 (0.9), 105 3 months: 5.3 (0.9), 105 6 months: 5.0 (0.8), 105	MD 0.00 (95% CI -0.23 to 0.23) MD -0.30 (95% CI -0.53 to -0.07) MD 0.00 (95% CI -0.22 to 0.22)
	Nocturia episodes per night	End of treatment: 0.5 (0.5), 105 3 months: 1 (0.9), 105 6 months: 1.5 (0.8), 105	End of treatment: 1.4 (0.8), 105 3 months: 1.5 (0.5), 105 6 months: 5 (0.8), 105	MD -0.90 (95% CO -1.08 to -0.72) MD -0.50 (95% CI -0.70 to -0.30) MD -3.50 (95% CI -3.72 to -3.28)
	Incontinence episodes per 24 hours	End of treatment: 1.4 (0.7), 105 3 months: 0.09 (0.28), 105. 6 months: 0.09 (0.28), 105.	End of treatment: 0.4 (0.6), 105 3 months: 0.5 (0.6), 105 6 months: 0.4 (0.6), 105	MD 1.00 (95% CI 0.82 to 1.18) MD -0.41 (95% CI -0.54 to -0.28) MD -0.31 (95% CI -0.44 to -0.18)
	Urgency episodes per 24 hours	End of treatment: 1.4 (0.7), 105 3 months: 1.6 (0.9), 105 6 months: 2 (0.8), 105	End of treatment: 4 (1.3), 105 3 months: 4.5 (1.5), 105 6 months: 4 (1.3), 105	MD -2.60 (95% CI -2.88 to -2.32) MD -2.90 (95% CI -3.23 to -2.57) MD -2.00 (95% CI -2.29 to -1.71)
Sancaktar 2010	Adverse effects	ES plus tolterodine: 1/20	Tolterodine: 2/18	RR 0.45 (95% CI 0.04 to 4.55)

Results in bold are statistically significant

¹Higher score = greater severity

Table 11. Electrical stimulation (ES) versus ES

Study	Outcome	ES A (mean (SD)/range), N or n/N; if available)	ES B (mean (SD), N or n/N; if available)	Result
Primary outcomes: cure/improvement of OAB symptoms; OAB-related quality of life				Primary outcome: quality of life
Alves 2015	ICIQ-OAB score ¹	Tibial nerve stimulation: sensory threshold activating superficial cutaneous nerve fibres with larger diameter: 4.46 (2.	Tibial nerve stimulation: motor threshold , non-painful contraction is induced: 4.53 (3.07), 13	MD -0.07 (95% CI -2.21 to 2.07)

Table 11. Electrical stimulation (ES) versus ES (Continued)

		66), 15		
Finazzi-Agrò 2005	Success = > 50% reduction in micturitions/24 hours OR If incontinent, success > 50% reduction in UI episodes/24 hours	ES once a week: 11/17 (4/11 incontinent participants)	ES 3 times per week: 12/18 (5/11 incontinent participants)	RR 0.97 (95% CI 0.60 to 1.57) Incontinence participants: RR 0.80 (95% CI 0.29 to 2.21)
	I-QoL score ²	ES once a week (median, range, N): 77 (35-100), 17	ES 3 times a week (median, range, N): 78 (33-100), 18	Not estimable
Lobel 1998	Participants with improvement in symptoms	ES once a week: 100%	ES twice a week: 100%	Not estimable
	Participants satisfied enough to request no further treatment	24% (9/37)		Not estimable, not reported per treatment group
Secondary outcomes: clinicians' observations and other quantification of symptoms				Secondary outcomes
Finazzi-Agrò 2005	Adverse effects	ES once a week: 0/17	ES 3 times per week: 0/18	Not estimable
	Subjective improvement after 6-8 sessions	ES once a week: 17/17	ES 3 times a week: 18/18	Not estimable
	Incontinence episodes per 24 hours	ES once a week (median, range, N): 1 (0-3), 11	ES 3 times a week (median, range, N): 1 (0-3), 11	Not estimable
	Micturitions per 24 hours	ES once a week (median, range, N): 8 (5-15), 17	ES 3 times a week (median, range, N): 8 (6-18), 18	Not estimable
	SF-36 score	ES once a week (median, range, N): 62 (24-81), 17	ES 3 times per week (median, range, N): 62 (25-80), 18	Not estimable
Alves 2015	UUI episodes per 24 hours	Tibial nerve stimulation: sensory threshold activating superficial cutaneous nerve fibres with larger diameter: 0.33 (0.57), 15	Tibial nerve stimulation: motor threshold, non-painful contraction is induced: 0.84 (1.39), 13	MD -0.51 (95% CI -1.32 to 0.30)
	Urgency episodes per 24 hours	Tibial nerve stimulation: sensory threshold activat-	Tibial nerve stimulation: motor threshold, non-	MD 0.21 (95% CI -0.39 to 0.81)

Table 11. Electrical stimulation (ES) versus ES (Continued)

		ing superficial cutaneous nerve fibres with larger diameter: 0.79 (0.97), 15	painful contraction is induced: 0.58 (0.65), 13	
	Micturitions per 24 hours	Tibial nerve stimulation: sensory threshold activating superficial cutaneous nerve fibres with larger diameter: 8.33 (2.52), 15	Tibial nerve stimulation: motor threshold, non-painful contraction is induced: 7.89 (2.64), 13	MD 0.44 (95% CI -1.48 to 2.36)
	Nocturia episodes per night	Tibial nerve stimulation: sensory threshold activating superficial cutaneous nerve fibres with larger diameter: 1.26 (1.21), 15	Tibial nerve stimulation: motor threshold, non-painful contraction is induced: 1.05 (1.01), 13	MD 0.21 (95% CI -0.61 to 1.03)
Bower 1998	Maximum cystometric capacity	150 Hz: 351 (144), 16	10 Hz: 305 (146), 16	MD 46.00 (95% CI -54.48 to 146.48)
	Volume at first desire to void	150 Hz: 208.5 (132), 16	10 Hz: 154 (61), 16	MD 54.50 (95% CI -16.75 to 125.75)
Other outcomes		Other outcomes		
Boaretto 2011	Participants satisfied	200 µs pulse width: 17/22	500 µs pulse width: 11/16	RR 1.12 (95% CI 0.75 to 1.68)

¹Higher score = greater severity

²Lower score = greater severity

APPENDICES

Appendix I. Search strategies

Cochrane Incontinence Specialised Register

The terms that were used to search the Cochrane Incontinence Specialised Register are given below:

(({{DESIGN.CCT*}} OR {{DESIGN.RCT*}}) AND ({{INTVENT.PHYS.ELECTSTIM*}}) AND ({{TOPIC.URINE.INCON*}} OR {{TOPIC.URINE.OVERACTIVE*}})

All searches were of the keyword field of [Reference Manager 2012](#). Date of last search 10 December 2015.

Other searches

Some of the review authors (OLFG, RE, MOG, AK, JLA) also searched the following databases, details of the searches are below:

PubMed (inception to December 2013) and **CENTRAL** (2013, Issue 12) were searched on 12 December 2013 using the following search terms:

((Overactive Bladder) OR (Overactive Urinary Bladder) OR (Overactive Detrusor) OR (Overactive Detrusor Function) OR bladder OR (urinary bladder) OR (unstable bladder) OR (urge incontinence) OR (inhibits bladder) OR (Urinary Reflex Incontinence) OR (Urinary

Urge Incontinence) OR (Urge Incontinence) OR (Urinary Bladder Disease) OR (Urinary Bladder Diseases) OR (Bladder Diseases) OR (Bladder Disease)) **AND** ((Electrical Stimulation) OR (Electrical Stimulations) OR (Electric Stimulations) OR (Electric Stimulation) OR (Electric Stimulation Therapy) OR (Therapeutic Electrical Stimulation) OR Electrotherapy OR (Therapeutic Electric Stimulation) OR (Electrical Stimulation Therapy) OR (Transcutaneous Electrical Stimulation) OR (Percutaneous Electric Nerve Stimulation) OR (Percutaneous Electrical Nerve Stimulation) OR (Transdermal Electrostimulation) OR (Transcutaneous Electrical Nerve Stimulation) OR (Transcutaneous Nerve Stimulation) OR (Transcutaneous Electric Stimulation) OR TENS OR Electroanalgesia OR (Analgesic Cutaneous Electrostimulation))

Embase on OVID SP (from 1980 onwards) (searched on 12 December 2013)

The search strategy that was used in Embase is given below. The RCT terms (lines 1 and 2) are those recommended by [Lefebvre 2011](#). The search was limited to those records added to Embase from January 2010 onwards as earlier trials are included in the Specialised Register search of CENTRAL.

1. (random\$ or factorial\$ or crossover\$ or cross over\$ or cross-over\$ or placebo\$ or (doubl\$ adj blind\$) or (singl\$ adj blind\$) or assign\$ or allocat\$ or volunteer\$.tw.
2. (crossover-procedure or double-blind procedure or randomised controlled trial or single-blind procedure).sh.
3. 1 or 2
4. urine incontinence/ or mixed incontinence/ or stress incontinence/ or urge incontinence/
5. overactive bladder/
6. (Detrusor\$ or bladder\$ or incontinen\$ or continen\$).tw.
7. 4 or 5 or 6
8. (Electric\$ Stimulation\$ or Electric Stimulation or Electrotherap\$ or TENS or Electroanalgesia or electrostimulation\$ or nerve stimulation\$).tw.
9. electrostimulation/
10. electrostimulation therapy/
11. transcutaneous nerve stimulation/
12. 8 or 9 or 10 or 11
13. 3 and 7 and 12
14. 2010\$.em.
15. 2011\$.em.
16. 2012\$.em.
17. 2013\$.em.
18. 14 or 15 or 16 or 17
19. 13 and 18

LILACS (on the Virtual Health Library/Bireme) (from 1982 to December 2013) (searched on 12 December 2013).

The terms that were used to search LILACS are given below. The RCT terms are those developed by Castro and colleagues ([Castro 1997](#); [Castro 1999](#)).

(Detrusor\$ OR bladder\$ OR incontinen\$ OR continen\$) [Words]

AND

((Electric\$ Stimulation\$) OR (Electric Stimulation) OR Electrotherap\$ OR TENS OR Electroanalgesia OR electrostimulation\$ OR (nerve stimulation\$)) [Words]

(nb for some reason if remove (electric stimulation) it retrieves less articles!!!)

((Pt randomised controlled trial OR Pt controlled clinical trial OR Mh randomised controlled trials OR Mh random allocation OR Mh

double-blind method OR Mh single-blind method) AND NOT (Ct animal AND NOT (Ct human and Ct animal)) OR (Pt clinical trial OR Ex E05.318.760.535\$ OR (Tw clin\$ AND (Tw trial\$ OR Tw ensa\$ OR Tw estud\$ OR Tw experim\$ OR Tw investiga\$)) OR ((Tw singl\$ OR Tw simple\$ OR Tw doubl\$ OR Tw doble\$ OR Tw duplo\$ OR Tw trebl\$ OR Tw trip\$) AND (Tw blind\$ OR Tw cego\$ OR Tw ciego\$ OR Tw mask\$ OR Tw mascar\$)) OR Mh placebos OR Tw placebo\$ OR (Tw random\$ OR Tw randon\$ OR Tw casual\$ OR Tw acaso\$ OR Tw azar OR Tw aleator\$) OR Mh research design) AND NOT (Ct animal AND NOT (Ct human and Ct animal)) OR (Ct comparative study OR Ex E05.337\$ OR Mh follow-up studies OR Mh prospective studies OR Tw control\$ OR Tw prospectiv\$ OR Tw volunt\$ OR Tw volunteer\$) AND NOT (Ct animal AND NOT (Ct human and Ct animal))) [Words]

Field = words

Ongoing clinical trials were sought by searching the clinical trials registration sites [ClinicalTrials.gov](#) and [WHO ICTRP](#) using the search term: overactive bladder. The date of the most recent search was 12 December 2013.

WHAT'S NEW

Last assessed as up-to-date: 10 December 2015.

Date	Event	Description
10 February 2017	Amended	Minor amendment to results section 3 i) - we moved participant satisfaction under its own heading as it had got left in with the outcome above it

HISTORY

Protocol first published: Issue 9, 2012

Review first published: Issue 4, 2016

Date	Event	Description
29 November 2016	New citation required and conclusions have changed	For this first update of this review the main outcomes were reframed to: perception of cure or cure/improvement. The search was updated and 12 new studies were included. A brief economic commentary has also been added. The conclusions have changed
9 September 2015	New citation required and minor changes	The protocol has been amended.
9 September 2015	Amended	The protocol has been amended.

CONTRIBUTIONS OF AUTHORS

Conceiving the review: Joao Luiz Amaro (JLA)

Co-ordinating the review: JLA, Regina El Dib (RED), Fiona Stewart (FS)

Undertaking manual searches: Luís Felipe Orsi Gameiro (LFOG)

Screening search results: LFOG, FS, Monica Orsi Gameiro (MOG)

Organising retrieval of papers: LFOG

Screening retrieved papers against inclusion criteria: LFOG, FS, JLA, MOG, and RED

Appraising quality of papers: FS, LFOG, JLA, MOG, and RED

Abstracting data from papers: FS, LFOG, RED

Writing to authors of papers for additional information: FS, LFOG and Anil Kapoor (AK)

Providing additional data about papers: LFOG, MOG, AK, JLA

Obtaining and screening data on unpublished studies: LFOG

Data management for the review: FS, LFOG, JLA, MOG and RED

Data entry: FS, LFOG and RED

Statistical analysis using [RevMan 2014](#): FS, LFOG, JLA, MOG, and RED

Other statistical analysis not using [RevMan 2014](#): RED and AK

Interpretation of data: FS, LFOG, RED, MOG, AK, JLA

Statistical inferences: FS, LFOG, RED, MOG, AK, JLA

Writing the review: FS, LFOG, RED, MOG, AK, JLA

Guarantor for the review: RED

Reading and checking review before submission: FS, LFOG, RED, MOG, AK, JLA

DECLARATIONS OF INTEREST

Fiona Stewart: none known

Luís Felipe Orsi Gameiro: none known

Regina El Dib: none known

Monica Orsi Gameiro: none known

Anil Kapoor: none known

Joao Luiz Amaro: none known

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- No sources of support supplied

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Several aspects of the methods specified in the protocol were changed when conducting the review, partly due to practical considerations but mostly in response to advice from clinicians and methodologists.

Data collection and analysis

Time constraints and the large number of trials identified made it unfeasible to carry out the planned independent double data extraction and risk of bias assessment; instead, data extraction and risk of bias assessment were checked by a second reviewer.

Comparators

Electrical stimulation versus no active treatment, placebo or sham treatment: between the protocol and review stages it became apparent that it was not appropriate to treat these three comparators as one comparator. Placebo and sham treatment were considered similar enough to be grouped as one comparator while no active treatment was treated as an entirely separate comparator.

Comparison 6: ES plus another treatment versus no active treatment, placebo or sham treatment. Between publishing the protocol and conducting the review it became apparent that this comparison does not help to answer the primary research question of the effectiveness of electrical stimulation compared to other treatments because we would be unable to isolate the effects of ES from those of the other treatment under investigation.

Types of outcomes

Data relating to the following outcome, which was not a pre-specified outcome, were reported in the review:

- Number of participants satisfied with treatment

The following pre-specified secondary outcomes were no longer considered to be clinically relevant and were not included in the review.

- Pad tests
- Number of participants with objectively measured incontinence (such as observation of leakage, leakage observed at urodynamics study)
- Number of participants with detrusor overactivity observed at urodynamic study
- Bladder capacity measured by urodynamic study

Data analysis

We did not use standardised mean difference to combine trials that measured the same outcome with different methods.

We did not identify sufficient data to carry out the planned subgroup analyses:

- trials in people with OAB and/or UUI versus those with OAB, UUI and/or MUI; and
- trials in people with idiopathic OAB versus neurogenic OAB.

INDEX TERMS

Medical Subject Headings (MeSH)

Electric Stimulation Therapy [instrumentation; *methods]; Electrodes; Pelvic Floor; Randomized Controlled Trials as Topic; Urinary Bladder, Overactive [*therapy]; Urinary Incontinence, Urge [*therapy]

MeSH check words

Adult; Humans