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# Electrical stimulation with non-implanted devices for stress urinary incontinence in women (Protocol)

Stewart F, Berghmans B, Bø K, Glazener CMA

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[Intervention Protocol]

# Electrical stimulation with non-implanted devices for stress urinary incontinence in women

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## ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

To assess the effectiveness of electrical stimulation with non-implanted devices, alone or in combination with other treatment, in the management of stress urinary incontinence or stress-predominant mixed urinary incontinence in women.

## BACKGROUND

### Description of the condition

Urinary incontinence (UI) affects 25% to 45% of women worldwide (ICI 2013). UI presents in the following forms:

- Stress urinary incontinence (SUI): involuntary loss of urine through physical exertion or effort, coughing or sneezing
- Urgency urinary incontinence (UUI): involuntary loss of urine associated with a sudden and compelling desire (urgency) to urinate that is difficult to delay
- Mixed urinary incontinence (MUI): involuntary loss or urine associated with both stress and urgency

Symptomatic diagnosis of SUI is typically based on whether urine leakage occurs with physical exertion or effort, as reported by women themselves.

In addition, urodynamically proven stress incontinence (USI) is diagnosed when urine leakage is seen by an observer on stress such as coughing during urodynamic examination, in the absence of a detrusor contraction (ICI 2013). Symptomative diagnosis of MUI is based on self-report of urine leakage through both physical exertion and urgency.

This review will include women with SUI, USI and stress-predominant MUI.

Several mechanisms are thought to contribute to stress urinary incontinence:

- suboptimal pelvic floor muscle strength
- hypermobility or significant displacement of the urethra and bladder neck during exertion
- intrinsic urethral sphincter deficiency (ICI 2013).

In women, these mechanisms may coexist (Kursh 1994) but few clinical trials have distinguished between these underlying causes. We will consider women whose incontinence may be due to any

of these mechanisms together in this review.

Prevalence estimates of SUI range from 3% to 25% of adult women, with older women more likely to be affected (ICI 2013). Quality of life and sexual function are often substantially impaired by SUI (Oh 2008). The ability to carry out daily activities can be severely impacted by SUI, resulting in debilitating embarrassment, social isolation and considerably decreased health-related quality of life (Bartoli 2010). Women with SUI may be less likely to participate in physical activity, which in turn has a detrimental impact on overall health because inactivity is a risk factor for many diseases (Bø 2004). Other evidence has shown that up to 50% of women with UI will avoid intimacy with their partners (Roos 2014).

Furthermore, SUI is associated with a considerable economic burden for women and for healthcare providers. For instance, routine care, such as pads, can cost several hundreds of pounds a year for each woman affected, while conservative treatment and surgery each cost several thousand pounds for each woman (ICI 2013).

## Description of the intervention

In Europe and the USA, conservative interventions such as pelvic floor muscle training (PFMT), with or without biofeedback, are recommended as first-line treatment for SUI (EAU 2015; NICE 2013; Qaseem 2014); however, many women may find it difficult to adhere to these methods in the long term (Bø 2005; Dumoulin 2014).

Surgery is usually suggested as a second-line option where conservative treatment has not improved a woman's symptoms or she is unwilling or unable to continue the treatment. Synthetic mid-urethral tape, open or laparoscopic colposuspension and autologous rectus fascia sling procedures are recommended by the National Institute for Health and Care Excellence (NICE), although the use of surgery with tapes in the management of UI remains controversial in terms of safety and adverse effects (Scottish Government 2015). The effectiveness of surgical management for SUI has been investigated by several Cochrane Reviews (Dean 2006; Lapitan 2012; Nambiar 2014; Rehman 2011). Other older surgical procedures, such as anterior repair or bladder neck needle suspension, have generally been superseded due to lower effectiveness.

Other less invasive second-line treatment options available in some countries include bulking agents, where a substance is injected into the urethral wall to increase its size and allow it to remain closed, or pharmacological therapy, typically with duloxetine. The disadvantages of these treatments are that they are likely to be less effective than surgery, and, in the case of drug therapy, long-term adherence is usually necessary, and is associated with unpleasant side effects (Alhasso 2005; Mariappan 2005). Bulking agents can cause discomfort or bleeding when urinating and their effectiveness decreases over time, requiring retreatment. Other available treatments for SUI include artificial urinary sphincters, and complementary therapies such as acupuncture.

It has been suggested that electrical stimulation (ES) could be used as a first-line treatment instead of PFMT in women who are unable to contract their pelvic floor muscles voluntarily, or if PFMT alone is not sufficiently effective. It may also be beneficial to combine ES with the use of vaginal cones and drug therapy.

## How the intervention might work

When a nerve is stimulated, signals travel both toward the periphery and toward the central nervous system. Electrical stimulation may elicit responses to these signals, which may come from the central nervous system or the tissues innervated by the nerve, or the central nervous system may be modified to reinterpret some signals (Chancellor 2002; Fall 1994).

With respect to lower urinary tract dysfunctions, electrical stimulation is applied particularly to the pelvic floor muscles, bladder and sacral nerve roots. In the context of SUI, the aim of ES is to improve pelvic floor muscle strength so that the pelvic floor muscles can be recruited when needed to occlude the urethra (such as before a cough) and to increase muscle bulk, which may help reduce urine loss by coapting the urethral walls. Direct ES of the pelvic floor is intended to stimulate motor-efferent fibres of the pudendal nerve, which may elicit a direct contraction of the pelvic floor muscles or the striated peri-urethral musculature, supporting the intrinsic part of the urethral sphincter-closing mechanism ((Fall 1991; Scheepens 2003). As such, ES might contribute to the compensation of a weak intrinsic sphincter, but it is questionable whether or not ES in such cases would be the first-choice treatment option or would have any additional value to pelvic floor muscle training (Ayeleke 2015).

It has been suggested that ES restores continence in women with SUI by:

- strengthening the structural support of the urethra and the bladder neck (Plevnik 1991);
- securing the resting and active closure of the proximal urethra (Erlandson 1977);
- strengthening the pelvic floor muscles (Sand 1995);
- inhibiting reflex bladder contractions (Berghmans 2002; Fall 1994);
- modifying the vascularity of the urethral and bladder neck tissues (Fall 1991; Fall 1994; Plevnik 1991).

In the context of conservative or non-surgical, non-medical therapy, ES can be applied using surface electrodes in the form of transcutaneous or percutaneous ES. Transcutaneous ES is administered via suprapubic or vulval surface electrodes, or vaginal/anorectal plug electrodes; while percutaneous ES uses needle electrodes in conjunction with a surface electrode placed close to the needle to act as a reference electrode, e.g. posterior tibial nerve stimulation, percutaneous nerve evaluation.

The frequency, dosage and duration of treatment with ES varies considerably. Although success has been claimed for a wide range of

parameters, the optimal set of parameters for each type of urinary incontinence has not been determined. Clinical consensus from the International Consultation on Incontinence (ICI) underlines this uncertainty:

"EStim is provided by clinic-based mains powered machines or portable battery powered stimulators with a seemingly infinite combination of current types, waveforms, frequencies, intensities, electrode types and placements. Without a clear biological rationale it is difficult to make choices about different ways of delivering EStim. Additional confusion is created by the relatively rapid developments in the area of EStim, and a wide variety of stimulation devices and protocols have been developed even for the same condition" (ICI 2013).

Evidence from a systematic review has suggested that, in men, ES with non-implanted devices is more effective than sham treatment for urinary incontinence and that ES enhances the effectiveness of pelvic floor muscle training in the short term (Berghmans 2013). Other evidence suggests that ES is more effective than sham, placebo or no active intervention in the treatment of overactive bladder and urgency urinary incontinence (Stewart 2016). It is not yet clear whether ES has similar effects in women with SUI.

### Why it is important to do this review

ES has shown promise in the treatment of UUI, but the evidence base for its use in treating SUI is inconclusive (Schreiner 2013). Given the adherence issues with conservative treatment, the side effects of drug therapy and the safety concerns regarding some kinds of surgical intervention, it is important to investigate alternative options for women with SUI.

Many randomised controlled trials (RCTs) have been undertaken investigating ES for SUI, compared to a variety of conservative interventions for SUI such as pelvic floor muscle exercises, drug therapy, vaginal cones, sham ES and no active treatment. Some trials have found no evidence of a difference in treatment effect, while others have found ES to be more effective than a comparator intervention. Given the heterogeneity of ES treatments, it is important to attempt to synthesise the available evidence relating to the diverse ES devices and protocols. Some of the earlier evidence relating to ES for SUI in women has been synthesised in previous publications (ICI 2013; Imamura 2010), but with a growing number of trials addressing this question an up-to-date and comprehensive systematic review is needed to obtain the best possible estimate of the effectiveness of ES.

## OBJECTIVES

To assess the effectiveness of electrical stimulation with non-implanted devices, alone or in combination with other treatment, in the management of stress urinary incontinence or stress-predominant mixed urinary incontinence in women.

## METHODS

### Criteria for considering studies for this review

#### Types of studies

Parallel or cross-over RCTs, quasi-RCTs (RCTs in which allocation to treatment is by methods such as alternate medical records, date of birth, or other predictable methods) and cluster-randomised trials will be eligible for inclusion.

To critically appraise and summarise current evidence on the cost effectiveness of ES we will also include relevant health economics studies conducted alongside effectiveness studies that meet the eligibility criteria for the effectiveness component of the review. This includes:

- full economic evaluation studies of ES compared to other treatments (i.e. cost-effectiveness analyses, cost-utility analyses, cost-benefit analyses)
- partial economic evaluations of ES (i.e. cost analyses, cost-description studies, cost-outcome descriptions)
- RCTs reporting more limited information, such as estimates of resource use or costs associated with ES

#### Types of participants

Eligible studies will include adult women (18 years or older, or according to study authors' definitions of adult) with SUI or stress-predominant MUI on the basis of symptoms, signs or urodynamic diagnosis. The trialists will define the criteria used to classify women with SUI or stress-predominant MUI.

We will exclude studies of women with urgency-predominant MUI, UUI only, or incontinence associated with a neurologic condition or frailty. We will also exclude studies in men and women where data are not reported separately by sex. We will exclude studies including only men or children. We will include trials of participants with MUI, UUI and SUI only if the data for women with SUI are presented separately. We will include trials in women with MUI if the condition is SUI-predominant.

#### Types of interventions

Eligible interventions will include any method of delivering electrical stimulation with non-implanted devices.

We will exclude trials of magnetic stimulation and electroacupuncture.

Eligible comparators will be no active treatment, placebo or sham treatment, or any intervention intended to decrease SUI, including conservative treatment (including complementary therapies, pelvic floor muscle training (PFMT) and vaginal cones), drug therapy and surgery. We will also include studies comparing different ES methods. There will be no restrictions by type of device, stimulation parameters (such as continuous, interrupted, duration of stimulation), duration of treatment, route of administration (vaginal, rectal, skin, pretibial area, etc.), or other similar factors. We will exclude trials of different combinations of treatments if it is not possible to identify the effect of the ES intervention (e.g. ES plus another treatment versus other combined treatments).

We will make the following comparisons:

1. ES versus no active treatment
2. ES versus placebo or sham treatment
3. ES versus other conservative treatment (e.g. bladder training, PFMT, biofeedback, magnetic stimulation)
4. ES versus drugs (e.g. duloxetine)
5. ES versus surgery or injection of bulking agents
6. ES plus another treatment versus the other treatment alone
7. One type of ES versus another

We will not include studies where the comparator interventions, alone or as a supplement to ES, are different in the intervention and control arms (i.e. ES plus another treatment A versus a different other treatment B, with or without ES).

## Types of outcome measures

We will extract outcome data reported at the end of treatment and at the end of the longest available follow-up period. We will consider the following outcomes:

### Primary outcomes

- Cure: number of women with self-reported continence
- Improvement: number of women with self-reported improvement in SUI (cured or improved)
- Incontinence-specific quality-of-life (QoL) measures (however defined by authors or by any validated measurement scales such as International Consultation on Incontinence Questionnaire (www.iciq.net))

### Secondary outcomes

1. Satisfaction with treatment
2. Need for further treatment
3. QoL measures of general health status, e.g. SF-36
4. Quantification of symptoms (e.g. number of incontinence episodes (every 24 hours), number of micturitions every 24 hours, pad tests)
5. Socioeconomic measures (e.g. costs of interventions, cost effectiveness of interventions in terms of incremental cost-effectiveness ratios (ICERs), costs per quality-adjusted life year (QALY) or cost-benefit ratios)
6. Adverse effects (e.g. skin or tissue damage, pain or discomfort, vascular, visceral or nerve injury, voiding dysfunction)

### Tertiary outcomes

We will extract data related to the following assessments as indirect measures of the physiological effect of treatment:

1. Clinicians' observations e.g. objectively-measured cure or improvement, incontinence (such as observation of leakage, leakage observed at urodynamics study)
2. Pelvic floor muscle strength or ability to contract the pelvic floor muscles, or both
3. Any other outcomes judged important when performing the review.

### Main outcomes for 'Summary of findings' table

We will apply the principles of the GRADE system (Guyatt 2008) to assess the quality of the body of evidence. This approach uses four categories (very low, low, moderate and high) to rate the quality of evidence available for selected outcomes; for instance evidence from RCTs is initially judged to be high quality but this can be downgraded if there are other indications of low quality, such as small sample sizes or high risk of bias.

We will include the following outcomes in a 'Summary of findings' table:

1. Number of women with self-reported continence
2. Number of women with self-reported improvement in SUI
3. QoL measures due to SUI
4. Adverse effects: pain or discomfort due to treatment
5. Cost effectiveness of interventions

## Search methods for identification of studies

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

### Electronic searches

This review will draw on the search strategy developed for the Cochrane Incontinence Group. We will identify relevant trials from the Cochrane Incontinence Group Specialised 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 ICTRP and handsearching of journals and conference proceedings. Most of the trials in the Cochrane Incontinence Group Specialised Register are also contained in CENTRAL.

The terms that we will use to search the Incontinence Group Specialised Register are given in Appendix 1.

#### Cost-effectiveness searches

We will also undertake separate searches to identify studies examining the cost effectiveness of ES for SUI. Databases to be searched will include: Health Management Information Consortium (HMIC), Cost-Effectiveness Analysis Registry (CEA Registry) and Research Papers in Economics (RePEc).

### Searching other resources

We will check the reference lists of the identified relevant studies for additional citations. We will consult with clinical specialists and will contact the authors of included trials where appropriate, to obtain unpublished data or to seek clarification on ambiguous data in published trial reports.

## Data collection and analysis

### Selection of studies

Two authors will independently screen the trials identified by the literature search, resolving any disagreements by discussion or by referring to a third party.

### Data extraction and management

Two authors will extract data independently, resolving any disagreements by discussion or by referring to a third party. We will use a standard data extraction form to extract data on study characteristics (design, methods of randomisation), participants, interventions and outcomes.

### Assessment of risk of bias in included studies

We will assess risks of bias with the Cochrane 'Risk of bias' tool (Higgins 2011), which addresses the following kinds of bias:

- Selection bias (randomisation and allocation concealment)
- Performance bias (blinding of participants, caregivers)
- Detection bias (blinding of outcome assessors)
- Attrition bias (incomplete outcome data or differential withdrawal)
- Reporting bias (selective reporting of outcomes)

Two authors will independently carry out 'Risk of bias' assessment and will resolve any disagreements by consulting a third author.

### Measures of treatment effect

For dichotomous data, we will calculate the risk ratio (RR) with a 95% confidence interval (CI). For continuous data, we will present the mean difference (MD) with a 95% CI. We will calculate the standardized mean difference (SMD) to combine trials that measure the same outcome but with different methods.

### Unit of analysis issues

We will analyse studies with non-standard designs, such as cross-over trials and cluster-randomised trials, as described in the *Cochrane Handbook for Systematic Reviews of Interventions (*Higgins 2011). We will analyse studies with multiple treatment groups by treating each pair of arms as a separate comparison, as appropriate. Where data from randomised cross-over trials are incomplete we will consider including data from the first period of randomisation only.

The unit of analysis will be each participant recruited into the trials.

### Dealing with missing data

We will analyse 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 are excluded after allocation or withdraw from the trial, we will report any details provided in full. Where data from randomised cross-over trials are incomplete we will consider including data from the first period of randomisation only.

Where trials report mean values without standard deviations (SDs) but with P values or 95% CIs, we will use the Review Manager 5 calculator to estimate the SD. Where trials report mean values only, we will assume the outcome to have a SD equal to the highest SD from the other trials within the same analysis.

We will make all reasonable attempts to contact authors for clarification of missing data.

### Assessment of heterogeneity

We will assess clinical heterogeneity by examination of the trial methods, and test for statistical heterogeneity between trial results using the $Chi^2$ test and the $I^2$ statistic, with the following cut-offs (Higgins 2011):

- < 30% heterogeneity may not be important
- 30% to 50% may represent moderate heterogeneity
- > 50% may represent substantial heterogeneity

### Assessment of reporting biases

We will assess the likelihood of potential publication bias using funnel plots, provided that we identify 10 or more eligible trials contributing to an outcome.

### Data synthesis

We will use the fixed-effect model to analyse data. If we identify significant heterogeneity (for example $I^2$ higher than 50%), we will compute pooled estimates of the treatment effect for each outcome under a random-effects model.

### Subgroup analysis and investigation of heterogeneity

If data permit, we will carry out the following subgroup analyses:

- Population: trials with participants with SUI only versus participants with MUI
- Different approaches to electrode placement (transcutaneous (e.g. perineal skin, sacral), versus vaginal or anorectal)

Where we find substantial heterogeneity ($I^2$ > 50%), we will investigate the possible causes and carry out subgroup analyses as appropriate.

### Sensitivity analysis

If data permit, we will perform sensitivity analysis comparing trials at low risk of selection bias to those at high risk of selection bias, which will explore the robustness of the results.

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* *Indicates the major publication for the study*

# APPENDICES

## Appendix 1. Search strategy

### Cochrane Incontinence Group Specialised Register

The terms that will be used to search the Incontinence Group Specialised Register are given below:
(({DESIGN.CCT*} OR {DESIGN.RCT*}) AND {INTVENT.PHYS.ELECTSTIM*} AND {TOPIC.URINE.INCON*})
(All searches will be of the keyword field of Reference Manager 2012).

### Cost-effectiveness searches

Embase, MEDLINE In-Process & Other Non-Indexed Citations, MEDLINE
Ovid multifile search
1. exp "costs and cost analysis"/
2. economics/
3. exp economics,hospital/
4. exp economics,medical/
5. economics,pharmaceutical/
6. exp budgets/
7. exp models, economic/
8. exp decision theory/
9. ec.fs.
10. monte carlo method/
11. markov chains/
12. exp health status indicators/
13. cost$.ti.
14. (cost$ adj2 (effective$ or utilit$ or benefit$ or minimis$)).ab.
15. economic$ model$.tw.
16. (economic$ or pharmacoeconomic$ or pharmaco-economic$).tw.
17. (price$ or pricing).tw.
18. (financial or finance or finances or financed).tw.
19. ((value adj2 money) or monetary).tw.
20. markov$.tw.
21. monte carlo.tw.
22. (decision$ adj2 (tree? or analy$ or model$)).tw.
23. (standard adj1 gamble).tw.

24. trade off.tw.
25. or/1-22
26. electrostimulation/
27. Electric Stimulation/
28. neuromodulation/
29. (electrical stimulation or neuromodulation or ((percutaneous or transcutaneous) adj4 stimulation)).tw.
30. or/26-29
31. urine incontinence/ or mixed incontinence/ or stress incontinence/
32. urinary incontinence/ or urinary incontinence, stress/
33. ((stress or urinary) adj3 incontinence).tw.
34. or/31-33
35. 25 and 30 and 34
36. 35 not (letter or comment$ or editorial or note).pt.

## CONTRIBUTIONS OF AUTHORS

Fiona Stewart: draft protocol, screen search results, data extraction, data analysis, draft manuscript.

Bary Berghmans: review protocol, clinical advice, review analysis, review manuscript.

Kari Bo: review protocol, review analysis, review manuscript.

Cathryn MA Glazener: screen search results, data extraction, data analysis, draft manuscript.

## DECLARATIONS OF INTEREST

Fiona Stewart: none known

Bary Berghmans: none known

Kari Bø : none known

Cathryn MA Glazener: none known

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