

**Cochrane** Database of Systematic Reviews

# Electrical stimulation for faecal incontinence in adults (Review)

Hosker G, Cody JD, Norton CC

Hosker G, Cody JD, Norton CC. Electrical stimulation for faecal incontinence in adults. *Cochrane Database of Systematic Reviews* 2007, Issue 3. Art. No.: CD001310. DOI: 10.1002/14651858.CD001310.pub2.

www.cochranelibrary.com



# TABLE OF CONTENTS

HEADER	1
ABSTRACT	1
PLAIN LANGUAGE SUMMARY	2
BACKGROUND	3
OBJECTIVES	3
METHODS	3
RESULTS	5
DISCUSSION	6
AUTHORS' CONCLUSIONS	6
ACKNOWLEDGEMENTS	7
REFERENCES	8
CHARACTERISTICS OF STUDIES	9
DATA AND ANALYSES	14
Analysis 2.2. Comparison 2 ELECTRICAL STIMULATION versus ANY OTHER TREATMENT, Outcome 2 Number of people with no improvement in incontinence status (worse or unchanged).	16
Analysis 4.1. Comparison 4 ELECTRICAL STIMULATION AS AN ADJUNCT versus ANY OTHER TREATMENT, Outcome 1 Number of people failing to achieve full continence (worse, unchanged or improved).	19
Analysis 4.2. Comparison 4 ELECTRICAL STIMULATION AS AN ADJUNCT versus ANY OTHER TREATMENT, Outcome 2 Number of people with no improvement in incontinence status (worse or unchanged).	19
APPENDICES	20
WHAT'S NEW	20
HISTORY	20
CONTRIBUTIONS OF AUTHORS	21
DECLARATIONS OF INTEREST	21
SOURCES OF SUPPORT	21
INDEX TERMS	21



#### [Intervention Review]

# **Electrical stimulation for faecal incontinence in adults**

Gordon Hosker<sup>1</sup>, June D Cody<sup>2</sup>, Christine C Norton<sup>3</sup>

<sup>1</sup>The Warrell Unit, St Mary's Hospital, Manchester, UK. <sup>2</sup>Cochrane Incontinence Review Group, University of Aberdeen, Foresterhill, UK. <sup>3</sup>Physiology Unit, St Mark's Hospital, Harrow, UK

**Contact address:** Gordon Hosker, The Warrell Unit, St Mary's Hospital, Hathersage Road, Manchester, M13 OJH, UK. Gordon.Hosker@CMMC.nhs.uk.

**Editorial group:** Cochrane Incontinence Group. **Publication status and date:** Edited (no change to conclusions), published in Issue 1, 2009.

**Citation:** Hosker G, Cody JD, Norton CC. Electrical stimulation for faecal incontinence in adults. *Cochrane Database of Systematic Reviews* 2007, Issue 3. Art. No.: CD001310. DOI: 10.1002/14651858.CD001310.pub2.

Copyright © 2009 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

# ABSTRACT

# Background

Faecal incontinence is a particularly embarrassing and distressing condition with significant medical, social and economic implications. Electrical stimulation has been used with apparent success in the treatment of faecal incontinence. However, standards of treatment are still lacking and the magnitude of alleged benefits has yet to be established.

#### Objectives

To determine the effects of electrical stimulation for the treatment of faecal incontinence in adults.

#### Search methods

We searched the Cochrane Incontinence Group Specialised Trials Register (searched 13 March 2007) and reference lists of potentially eligible articles.

#### **Selection criteria**

All randomised or quasi-randomised trials evaluating electrical stimulation in adults with faecal incontinence.

## Data collection and analysis

Two reviewers assessed the methodological quality of potentially eligible trials and independently extracted data from the included trials. A wide range of outcome measures were considered.

#### **Main results**

Four eligible trials with 260 participants were identified. Findings from one trial suggest that electrical stimulation with anal biofeedback and exercises provides more short-term benefits than vaginal biofeedback and exercises for women with obstetric-related faecal incontinence. Another study found contradictory results, with no added benefit from electrical stimulation over biofeedback and exercises alone. Although all trials report that patient's symptoms are generally improved, it is not clear that this is the effect of electrical stimulation. No further conclusions could be drawn from the data available.

#### Authors' conclusions

At present, there are insufficient data to allow reliable conclusions to be drawn on the effects of electrical stimulation in the management of faecal incontinence. There is a suggestion that electrical stimulation may have a therapeutic effect, but this is not certain. Larger, more generalisable trials are needed.

# PLAIN LANGUAGE SUMMARY

## Electrical stimulation for faecal incontinence in adults

Faecal incontinence (inability to control bowel movements or leaking stool from the anus) can be a very embarrassing and socially restricting problem. There are many possible causes, including childbirth damage to the muscles which control bowel movements. Direct electrical stimulation of these muscles has been used to try to help people with faecal incontinence. The review found that there is not enough evidence from trials to judge whether electrical stimulation is helpful. Exercises and electrical stimulation used in the anus may be more helpful than vaginal exercises for women with faecal incontinence after childbirth.



# BACKGROUND

#### **Description of the condition**

Faecal incontinence has been variously defined. An international consensus meeting has recommended: "Faecal incontinence is the involuntary loss of liquid or solid stool that is a social or hygienic problem" (Norton 2005).

Faecal incontinence is a common health care problem, affecting 5% to 10% of community-dwelling adults (Perry 2002), with 1% to 2% experiencing significant impact on daily activities (Perry 2002). It becomes more common with advancing age and disability (Potter 2002). It is a symptom which is particularly embarrassing and socially unacceptable, and many sufferers do not seek professional help (Johanson 1996). Faecal incontinence has a major negative impact on physical and psychological health and lifestyle, with severe social restriction in many instances (Rockwood 1999; Rockwood 2000).

Faecal incontinence has many possible causes, including: obstetric or other trauma or congenital abnormality of one or both of the anal sphincters; loose stool or intestinal hurry; neurological disease or injury causing sensory or motor impairment to the continence mechanism; local anorectal pathology; rectal loading and subsequent "overflow" leakage in frail or immobile individuals; and physical or mental disabilities impairing toilet access. For many people, a combination of structural, physiological and psychosocial factors (Tuteja 2004; Norton 2004) combine to cause faecal incontinence.

It is generally recognised that symptoms may be of urgency with urge faecal incontinence (usually consequent upon external striated voluntary sphincter weakness or disruption, or intestinal hurry); or of passive soiling in the absence of an urge to defaecate, secondary to smooth muscle internal anal sphincter dysfunction, local pathology or incomplete evacuation. Recent advances in investigation techniques (notably ano-rectal physiology studies and endo-anal ultrasound) allow more accurate characterisation of the underlying cause for each patient. However, for many conditions, treatment options are limited, relying mainly on surgery and constipating drugs (Madoff 2005; Norton 2005; Whitehead 2001)

#### Description of the intervention and how it might work

Pelvic floor muscle training with or without electrical stimulation is a well-established therapy for the treatment of urinary incontinence (Hay-Smith 2006; Laycock 2002; Wilson 2005), but has been less commonly reported for faecal incontinence. The external anal sphincter is continuous with the puborectalis muscle and as a striated muscle, is theoretically amenable to the same re-educative techniques. The purpose of electrical stimulation is stated variously as enhancing the strength, speed, or endurance of voluntary anal sphincter contraction, or to enhance sensation and thus the ability to perform exercises or voluntarily contract the anal sphincter in response to an urge to defaecate.

Electrical stimulation has been used with apparent success in several case series for the treatment of faecal incontinence. It is administered in different ways, using many different stimulation parameters and is often used in conjunction with other therapies. The precise mechanisms by which electrical stimulation can restore faecal control are not well-understood. Electrical stimulation is known to improve muscle function by transforming fatigable fasttwitch muscle fibres to less-fatigable slow-twitch fibres (Salmons 1969) and it also increases capillary density (Hudlicka 1982) which supports the efficient working of these slow, oxidative fibres. Changes in fibre diameter may be important. However, apart from physiological changes, it may be that the predominant mechanism of improved faecal control is an enhanced awareness of the anal sphincter (Haskell 1967).

In spite of the poor understanding of the mechanisms involved, the results of observational studies are encouraging. However, the literature is sparse. There have been a few controlled trials, most studies are case reports (Konsten 1995). Electrical stimulation is often used in conjunction with other therapies such as biofeedback (Herold 1989) or anal sphincter exercises. Although it is possible to compare the results from an active device with those of a sham device, it is practically difficult to use a placebo. There has been no standardisation of the patterns of stimulation or the electrodes used and there is little in the way of long-term follow-up or validated outcome measurements.

The aim of the present review is to systematically search for and combine evidence from all relevant randomised controlled trials of electrical stimulation for the treatment of faecal incontinence in order to provide the best evidence currently available on which to base recommendations for clinical practice.

# OBJECTIVES

To determine the effectiveness of electrical stimulation in the treatment of faecal incontinence in adults. The following hypotheses have been considered.

1. Electrical stimulation is better than no treatment in alleviating faecal incontinence.

2. Electrical stimulation is better than other treatments in alleviating faecal incontinence.

3. Electrical stimulation used as an adjunct to another treatment is better than the electrical stimulation alone.

4. Electrical stimulation used as an adjunct to another treatment is better than that treatment on its own.

5. One modality of electrical stimulation is better than other modalities of electrical stimulation.

### METHODS

#### Criteria for considering studies for this review

#### **Types of studies**

All randomised or quasi-randomised controlled trials of electrical stimulation for the treatment of faecal incontinence in adults

#### **Types of participants**

All men and women aged 18 or over with the symptom of faecal incontinence.

# **Types of interventions**

The experimental group involved the use of external or intra-anal or intra-vaginal electrodes to deliver electrical stimulation.

**Electrical stimulation for faecal incontinence in adults (Review)** Copyright © 2009 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

#### Types of outcome measures

1. Patient symptoms:

Incontinence status.

Frequency of incontinence.

Number of pad changes.

Incontinence score.

Occurrence of adverse effects.

#### 2. Patient satisfaction with outcome:

Self-report.

#### 3. Ano-rectal physiology measurements:

Resting anal pressure (pressure or EMG).

Pressure rise on voluntary contraction (pressure or EMG).

Duration of pressure rise on voluntary contraction (pressure or EMG).

EMG activity of external anal sphincter.

Rectal sensation assessment (by balloon distension and/or electrical means).

Saline retention test.

#### 4. Health status measures:

Psychological health measures e.g. HADS (Zigmond 1983).

Health-related quality of life measures e.g. SF-36 Scale (Ware 1993) or condition-specific measures.

Activities of daily living measures e.g. Barthel ADL Index (Wade 1988).

#### 5. Health economics:

Costs of interventions.

Resource implications.

Cost effectiveness or cost utility evaluation e.g. QALY (Weinstein 1977).

#### 6. Other outcomes:

Other outcome measures quoted by the review authors and judged to be important by the reviewers.

#### Search methods for identification of studies

This review has drawn on the search strategy developed for the Incontinence Review Group. Relevant trials were identified from the Group's Specialised Register of controlled trials which is described, along with the search strategy, under the Incontinence Group's details in *The Cochrane Library* (For more details please see the 'Specialized Register' section of the Group's module in The Cochrane Library). The register contains trials identified from MEDLINE, CINAHL, The Cochrane Central Register of Controlled Trials (CENTRAL) and handsearching of journals and conference proceedings. The Incontinence Group's trials register was searched using the Group's own keyword system, the search terms used were:

(topic.faecal.incon\*)
AND
({design.cct\*} OR {design.rct\*})
AND
({intvent.phys.electstim\*})
(All searches were of the keyword field of Reference Manager 9.5 N,
ISI ResearchSoft).

Date of the most recent search of the register for this review: 13 March 2007.

The trials in the Incontinence Group's Specialised Register are also contained in CENTRAL.

For an earlier version of this review extra specific searches were performed. These are detailed in Appendix 1.

We searched the reference lists of relevant articles for other possible relevant trials.

We did not impose any language or other limits on the searches.

## Data collection and analysis

# **Trials selection**

Three review authors (GH, CN, JC) examined all the citations and abstracts derived from the electronic searches. Reports of potentially relevant trials were retrieved in full. Both review authors independently applied the selection criteria to trial reports. Reviewers were not blind to the names of authors, institutions or journals. Any disagreements were resolved by discussion.

#### **Quality assessment**

The methodological quality of identified trials were assessed independently by three review authors (GH, CN, JC) taking into account the quality of random allocation concealment, the description of dropouts and withdrawals, whether data were analysed on an intention to treat basis, and whether therapists, participants or outcome assessors were blind to the treatments provided.

Any disagreements were resolved by discussion. Studies were excluded if they were not randomised or quasi-randomised controlled trials in adults. The excluded studies and the reasons for their exclusion are summarised in the Table of Excluded Studies.

#### **Data extraction**

Data extraction from the included trials was undertaken independently by three review authors (GH, CN, JC). Only published data have been used. Data were processed as described in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2005). Any difference of opinion was resolved by discussion between the reviewers or referred to the third reviewer.

#### Analysis

Data were analysed using the Meta View statistical programme in Review Manager (RevMan).

Cochrane Library

Trusted evidence. Informed decisions. Better health.

Relative risk and 95% confidence intervals were calculated for dichotomous outcomes using a fixed effect model. We planned to analyse continuous variables using mean and standard deviation values. Differences between groups were presented as weighted mean differences (WMD) with accompanying 95% confidence intervals.

All outcomes were reported in terms of unfavourable events. This implied that odds ratios less than one or a WMD less than zero suggested a reduction in unfavourable events (i.e. a beneficial treatment effect). Therefore the benefits of the experimental treatment were all displayed on the same side of the line of no effect.

# RESULTS

#### **Description of studies**

Four trials met the inclusion criteria.

One recruited a total of 40 women with obstetric-related faecal incontinence (Fynes 1999). It compared 12 weeks of vaginal pressure biofeedback and home exercises versus anal EMG biofeedback and home exercises in combination with intra-anal electrical stimulation. The trial did not include any long-term follow up data beyond the end of the intervention period. A second study of 60 women with early post-partum faecal incontinence (secondary to sphincter disruption in most) compared weekly intra-anal biofeedback plus exercises versus weekly intra-anal biofeedback plus electrical simulation plus exercises for 12 weeks (Mahony 2004).

One trial compared surgical levatorplasty with anal plug electrical stimulation over two years in 70 patients with "idiopathic" faecal incontinence (Osterberg 2004).

One trial compared daily anal electrical stimulation at 35 Hz versus "sham" stimulation at 1 Hz in 90 patients with a mixed aetiology for faecal incontinence. No exercises or biofeedback were used (Norton 2006a).

No economic data were reported in the trials.

Details regarding the design and methodology of the included trials are presented in the Table of Characteristics of Included Trials.

#### **Risk of bias in included studies**

All studies were randomised controlled trials. Three studies are considered to have adequately addressed pre-treatment allocation concealment (Mahony 2004; Osterberg 2004; Norton 2006a), while the fourth does not mention this (Fynes 1999). Because of the nature of the intervention, further blinding was impossible once the treatment commenced in three studies (Fynes 1999; Mahony 2004; Osterberg 2004); in the other study patients but not researchers were blinded as to group throughout treatment (Norton 2006a). Only one study reported results on an intention to treat analysis (Norton 2006a). One other study reported reasons for drop-outs (Osterberg 2004).

All trials had potential methodological flaws. In one trial (Fynes 1999) the two intervention groups were treated by different therapists. The outcome assessor was blind to the treatment of individual patients. However, there was no description of

exclusion criteria and no explanation of why one patient droppedout sometime during the study. Furthermore, the trial compared two very different types of intervention (vaginal pelvic floor manometric pressure biofeedback and home exercises with anal EMG biofeedback and home exercises in combination with anal electrical stimulation) and did not just measure any added effect of electrical stimulation.

## **Effects of interventions**

#### **Electrical stimulation versus no treatment**

No trials were found.

#### Electrical stimulation versus any other treatment

One trial was found (Osterberg 2004). Comparison between patients randomised to levatorplasty or electrical stimulation was made at 3, 12, and 24 months following treatment. Surgery was superior to electrical stimulation in improving incontinence at 3 months, but not at 12 or 24 months. There was no difference in urgency (visual analogue scale) or use of pads between the groups at any time point. Quality of life (physical and social handicap) was superior in the surgical group at all time points. There were no significant changes in physiological variables in either group but the between-group statistics were not given.

# Electrical stimulation as an adjunct versus electrical stimulation alone

No trials were found.

# Electrical stimulation as an adjunct versus any other treatment

Two trials were found (Fynes 1999, Mahony 2004). One (Fynes 1999) involved 40 women with impaired faecal continence after obstetric injury. It compared vaginal pelvic floor manometric pressure biofeedback and home exercises taught by a nurse (19 completed the trial) with anal EMG biofeedback and home exercises in combination with anal electrical stimulation taught and administered by a physiotherapist (20 completed the trial). At the 12-week assessment there was a significant difference in favour of the electrical stimulation group in respect of the number of people who became asymptomatic (RR 0.40 95% CI 0.17 to 0.91, comparison 04,01) or improved (RR 0.06 95% CI 0.00 to 0.91, comparison 04,02) in their incontinence status. Other outcomes were presented as median values and range (continence score) or as mean values and range (resting pressure, squeeze pressure, squeeze increment and vector symmetry). The estimation of the standard deviation from the range was not computed since this method can result in an over-estimation of the standard deviation. Further clarification was sought from the authors but no other information has been forthcoming.

The other study (Mahony 2004) recruited 60 women, 12 weeks after delivery, 54 of whom completed the 12 weeks treatment. There was a significant increase in anal squeeze pressure in both groups, but no significant change in resting pressure. The trial report stated both groups improved continence scores and some domains of quality of life. There was was no statistical difference in numbers achieving full continence status (comparison 04.01) and numbers of participants with no improvement in incontinence status (comparison 04,02).

**Electrical stimulation for faecal incontinence in adults (Review)** Copyright © 2009 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

# One modality of electrical stimulation versus any other modalities of electrical stimulation

One trial was found (Norton 2006a). Seventy of 90 patients completed the trial comparing eight weeks of daily anal stimulation at 35 Hz with daily stimulation at 1 Hz (no other adjunctive therapies were used). On an intention to treat analysis, there were no statistically significant differences in patients' rating of outcome, patients' rating of change in symptoms, frequency of incontinent episodes, manometric resting or squeeze pressures, comfort, satisfaction with treatment, impact on quality of life or patients' rating of bowel control after 8 weeks of stimulation. Sixty three per cent of patients who completed treatment felt that it had improved their symptoms to at least some extent, with no difference between the two groups. The authors conclude that any effect may be sensory rather than direct muscle strengthening, or alternatively a placebo effect.

# DISCUSSION

Randomised controlled trials are thought to provide sound evidence on the effects of health care interventions mainly because they can eliminate selection bias. The four included trials in this review appear to have adequately addressed this issue. However, conclusions are difficult to draw.

The authors' conclusion from one trial (Fynes 1999) that biofeedback training augmented by electrical stimulation is superior to sensory biofeedback alone in the treatment of impaired faecal continence after obstetric trauma calls for some caution. The group who had stimulation as an adjunct utilised anal EMG for biofeedback whilst the group without stimulation utilised vaginal pressure biofeedback. If both groups had used the same type of biofeedback then it would have been possible to disentangle the specific effect of electrical stimulation and the conclusion stated would have had some validity. With the methods used, the only appropriate conclusion is that after twelve weeks therapy, a group of women with impaired faecal continence after obstetric delivery have better continence scores and anal pressures when treated with anal EMG biofeedback augmented with electrical stimulation compared to women treated with vaginal pressure biofeedback. It may be that the biofeedback alone group would, in time, have achieved the same improvement as the augmented group. This study cannot address this because it only assessed changes at 12 weeks. Equally, because there is no long term follow-up, it cannot address whether any improvement achieved is maintained or deteriorates. Women were recruited from 3 to 28 months after delivery, and so it is possible that improvement in both groups was due to the natural history of symptoms, which may improve with no intervention over time. It is rather disappointing that these methodological limitations provide no indication as to whether electrical stimulation has any benefit as an adjunct (as the differences in improvement could be explained by the different types of biofeedback). It is also disappointing that inadequate reporting of the outcome measures prevented complete analysis using RevMan. Finally, because a no-treatment group was not included, it is impossible to know much of the improvement in either group was simply due to natural recovery after childbirth. The second obstetric-related study (Mahony 2004) had contradictory findings, with no difference found between biofeedback and exercises compared with the same treatment plus adjunctive electrical stimulation. However, as women were recruited at 12 weeks post-partum and there was no non-treatment

control group, there is the possibility that improvement was the result of natural resolution of symptoms rather than either intervention. No longer term follow up was included. As the majority of these women had ultrasound evidence of sphincter disruption, there may also be a limit to expectation of improvement from either of these treatments.

The study which compared two different stimulation parameters (Norton 2006a) found no difference between a frequency (35 Hz) which is commonly recommended for enhancing the function of striated muscle and stimulation at 1 Hz, which feels very similar (hence the possibility of blinding) but should not actually produce a tonic muscle contraction. Both parameters give sensory input; only the former should enhance muscle contraction. The finding of no difference between the groups may indicate that any therapeutic effect is sensory enhancement, or placebo effect. However, in clinical practice electrical stimulation would seldom be given in isolation without exercises and other advice, so this study does not give a clear indication of usefulness in clinical practice. Additionally, there was no follow-up as all patients progressed immediately to biofeedback therapy at the end of the trial period.

Another study concludes that surgery is superior to electrical stimulation (Osterberg 2004) on the basis of quality of life improvement (using a non-validated score). Other parameters, including continence improvement, use of pads and urgency were not different between the two groups at 24 months. However, in an unblinded study, this quality of life difference may reflect patient preference for a one-off operation compared to the necessity to attend for 12 sessions of electrical stimulation. Additionally, it would be unusual in clinical practice to use electrical stimulation without adjunctive exercises, but these are not mentioned in the report.

In the existing literature there are several reports from uncontrolled trials on the effects of electrical stimulation for the treatment of adults with faecal incontinence. It is not uncommon to encounter statements like "the international literature as well as our own results confirm that electric stimulation is effective and may be in special cases a major factor in the conservative treatment of anorectal incontinence" (Sprakel 1998). However, the fact that only four controlled trials were found in this review demonstrates that much work needs to be carried out to clearly determine the role of electrical stimulation in the treatment of patients with faecal incontinence.

#### AUTHORS' CONCLUSIONS

#### **Implications for practice**

It is not possible to draw conclusions for practice from the data analysed in this review. The review does not provide sufficient evidence on which to judge the effectiveness of electrical stimulation in the management of people with faecal incontinence. In particular there is not enough evidence on which to select patients suitable for this type of treatment, nor to know which modality of electrical stimulation is optimal.

Electrical stimulation and/or anal EMG biofeedback may be superior to vaginal pressure biofeedback in women with symptoms after childbirth (Fynes 1999). However, based on the available evidence these conclusions can only be tentative and another study suggested electrical stimulation does not augment biofeedback



alone (Mahony 2004). The studies included in this review did not report any adverse events except a few patients discontinuing because of discomfort. However, electrical stimulation should not be offered to patients with a cardiac pacemaker and caution needs to be exercised if it is to be considered for a pregnant patient (although it is extremely unlikely that any one would wish to treat a pregnant patient) and those with a history of pelvic malignancy. Occasionally, electrical stimulation can cause a tissue reaction at the site of the electrodes. This usually resolves speedily when stimulation is stopped.

Treatment options for faecal incontinence have not been the subject of well-designed trials. It is not clear whether biofeedback or pelvic floor muscle training offer any advantage over well-managed conservative interventions such as patient teaching or advice (Norton 2006b). Drug options are limited (Cheetham 2002).

#### Implications for research

There is a need for well-designed randomised controlled trials with adequate numbers, validated outcome measures and long-term follow-up examining the effectiveness of electrical stimulation to directly improve poorly functioning anal sphincters. If stimulation is shown to be effective (either on its own or as an adjunct to other therapy), then trials examining the pattern of stimulation and method of stimulation delivery (intra-anal, intra-vaginal, implanted electrodes, etc.) need to take place in order to identify the optimum therapy. Of course, comparisons will also have to be made with other treatment modalities such as medication and surgery and there is a need to characterise participants in detail so that judgements can be made on which treatments are of benefit to which diagnostic categories. Economic analysis should also be incorporated into future trials.

It is clear from examining the literature for this review that very little attention has been given to the patient's perspective on outcome and there is still no information on what patients view as a good or satisfactory outcome of treatment for faecal incontinence. This is an issue which should be addressed in all trials involving the treatment of faecal incontinence.

#### ACKNOWLEDGEMENTS

Sheila Wallace for help and advice with the electronic search strategy. Miriam Brazzelli who acted as co-reviewer on the first publication of this review.



# REFERENCES

#### References to studies included in this review

#### Fynes 1999 {published data only}

Fynes MM, Marshall K, Cassidy M, Behan M, Walsh D, O'Connell PR, O'Herlihy C. A prospective, randomized study comparing the effect of augmented biofeedback with sensory biofeedback alone on fecal incontinence after obstetric trauma. *Diseases of the Colon and Rectum* 1999;**42**(6):753-8; discussion 758-61. [MEDLINE: 99304944]

#### Mahony 2004 {published data only}

Mahony RT, Malone PA, Nalty J, Behan M, O'Connell PR, O'Herlihy C. Randomized clinical trial of intra-anal electromyographic biofeedback physiotherapy with intra-anal electromyographic biofeedback augmented with electrical stimulation of the anal sphincter in the early treatment of postpartum fecal incontinence. *American Journal of Obstetrics & Gynecology* 2004;**191**(3):885-90. [19215]

#### Norton 2006a {published data only}

Norton C, Gibbs A, Kamm MA. Randomized, controlled trial of anal electrical stimulation for fecal incontinence. *Diseases of the Colon & Rectum* 2006;**49**(2):190-6. [21601]

#### Osterberg 2004 {published data only}

Osterberg A, Edebol Eeg-Olofsson K, Hallden M, Graf W. Randomized clinical trial comparing conservative and surgical treatment of neurogenic faecal incontinence. *British Journal of Surgery* 2004;**91**(9):1131-7. [19250]

#### References to studies excluded from this review

#### George 1991 {published data only}

George BD, Patel J, Hallan RI, Watkins ES, Williams NS. Intermittent electrical stimulation of the gracilis neosphincter. *British Journal of Surgery* 1991;**78**(6):756.

#### Sprakel 1998 {published data only}

Sprakel B, Maurer M, Langer M, Diller R, Spiegel HU, Winde G. Effect of electrostimulation on sphincter function in fecal incontinence [Stellenwert der schwellstromtherapie im rahmen der konservativen behandlung der anorektalen inkontinenz]. Zentralblatt fur Chirurgie 1998;**123**:224-229.

#### Surh 1998 {published data only}

Surh S, Kienle P, Stern J, Herfarth C. [Passive electrostimulation therapy of the anal sphincter is inferior to active biofeedback training]. [German] [Die passive Elektrostimulationstherapie des Analsphinkters ist dem aktiven Biofeedbacktraining unterlegen]. *Langenbecks Archiv fur Chirurgie - Supplement - Kongressband* 1998;**115**:976-8. [MEDLINE: 99130556]

#### Williams 1991 {published data only}

Williams NS, Patel J, George BD, Hallan RI, Watkins ES. Development of an electrically stimulated neoanal sphincter. *Lancet* 1991;**338**(8776):1166-9. [MEDLINE: 92047876]

#### **References to ongoing studies**

#### Stott {published data only}

A study to determine the effects of neuro-stimulation on anal sphincter function when used in conjunction with biofeedback and pelvic floor exercises in the treatment of faecal incontinence. Ongoing study January 2000..

#### **Additional references**

#### Cheetham 2002

Cheetham M, Brazzelli M, Norton C, Glazener CMA. Drug treatment for faecal incontinence in adults. *Cochrane Database of Systematic Reviews* 2002, Issue 3. [Art. No.: CD002116. DOI: 10.1002/14651858.CD002116]

#### Haskell 1967

Haskell B, Rovner H. Electromyography in the managment of the incompetent anal sphincter. *Disease of the Colon and Rectum* 1967;**10**(2):81-4. [MEDLINE: 67125689]

#### Hay-Smith 2006

Hay-Smith EJC, Dumoulin C. Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women. *Cochrane Database of Systematic Reviews* 2006, Issue 1. [Art. No.: CD005654. DOI: 10.1002/14651858.CD005654]

#### Herold 1989

Herold A, Bruch HP, Hocht B, Muller G. Biofeedback training and functional electrostimulation for improving incontinence in children with anal atresia. *Langenbecks Archiv für Chirurgie. Supplement II, Verhandlungen der Deutschen Gesellschaft für Chirurgie. Deutsche Gesellschaft für Chirurgie. Kongress* 1989;**Supplement II**:991-5.

# Higgins 2005

Higgins JPT, Green S, editors. Cochrane Handbook for Systematic Reviews of Interventions 4.2.5 [updated May 2005]. The Cochrane Library. Chichester, UK: John Wiley & Sons, Ltd, 2005, Issue 3.

#### Hudlicka 1982

Hudlicka O, Dodd L, Renkin EM, Gray SD. Early changes in fiber profile and capillary density in long-term stimulated muscles. *American Journal of Physiology* 1982;**243**:528-35.

#### Johanson 1996

Johanson JF, Lafferty J. Epidemiology of faecal incontinence: the silent affliction. *American Journal of Gastroenterology* 1996;**91**(1):33-6.

#### Konsten 1995

Konsten J, Geerdes B, Versluis P, Heineman E, Baeten GM. Dynamic graciloplasty for restoration of continence after traumatic destruction of the rectum and sphincters: report of a case. *Journal of Trauma* 1995;**38**(1):11-3. [MEDLINE: 95264378]



#### Laycock 2002

Laycock J, Haslam J. Therapeutic management of incontience and pelvic pain. London: Springer, 2002.

#### Madoff 2005

Madoff RD, Pemberton JH, Mimura T, Laurberg S. Surgery for fecal incontinence. In: Abrams P, Cardoza L, Khoury S, Wein A editor(s). Incontinence: 3rd International Consultation on Incontinence. Plymouth: Health Publications, 2005:1565-88.

#### Norton 2004

Norton C, Chelvanayagam S. Bowel Continence Nursing. Beaconsfield: Beaconsfield Publishers, 2004.

#### Norton 2005

Norton C, Whitehead WE, Bliss DZ, Metsola P, Tries J. Conservative and pharmacological management of faecal incontinence in adults. In: Abrams P, Cardoza L, Khoury S, Wein A editor(s). Incontinence. Plymouth: Health Publications, 2005:1521-63.

#### Norton 2006b

Norton C, Cody JD, Hosker G. Biofeedback and/or sphincter exercises for the treatment of faecal incontinence in adults. *Cochrane Database of Systematic Reviews* 2006, Issue 3. [Art. No.: CD002111. DOI: 10.1002/14651858.CD002111.pub2]

#### Perry 2002

Perry S, Shaw C, McGrother C, Flynn RJ, Assassa RP, Dallosso H, et al. The prevalence of faecal incontinence in adults aged 40 years or more living in the community. *Gut* 2002;**50**:480-4.

#### Potter 2002

Potter J, Norton C, Cottenden A. Bowel care in older people. London: Royal College of Physicians, 2002.

#### Rockwood 1999

Rockwood TH, Church JM, Fleshman JW, Kane RL, Mavrantonis C, Thorson AG, et al. Patient and surgeon ranking of the severity of symptoms associated with fecal incontinence: the fecal incontinence severity index. *Disease of the Colon and Rectum* 2000;**43**:9-17.

#### Rockwood 2000

Rockwood TH, Church JM, Fleshman JW, Kane RL, Mavrantonis C, Thorson AG, et al. Fecal incontinence quality of life scale. *Diseases of the Colon and Rectum* 2000;**43**:9-17.

#### Salmons 1969

Salmons S, Vrbova G. The influence of activity on some contractile characteristics of mammalian fast and slow muscles. *Journal of Physiology* 1969;**201**(3):535-49. [MEDLINE: 69180292]

#### Tuteja 2004

Tuteja AK, Rao SS. Review article: recent trends in diagnosis and treatment of faecal incontinence. *Alimentary Pharmacol Therapy* 2004;**19**(8):829-40.

# Wade 1988

Wade DT, Collin C. The Barthel ADL Index: a standard measure of physical disability. *International Disabilities Studies* 1988;**10**(2):64-7. [MEDLINE: 88298624]

#### Ware 1993

Ware JE, Sherbourne CD. SF-36 Health Survey Manual and Interpretation Guide. Boston: New England Medical Centre, 1993.

#### Weinstein 1977

Weinstein MC, Statson WB. Foundations of cost-effectiveness analysis for health and medical practices. *New England Journal of Medicine* 1977;**296**(13):716-21. [MEDLINE: 77123720]

#### Whitehead 2001

Whitehead WE, Wald A, Norton N. Treatment options for fecal incontinence: consensus conference report. *Diseases of the Colon and Rectum* 2001;**44**:131-44.

#### Wilson 2005

Wilson PD, Berghmans B, Hagen S, Hay-Smith J, Moore K, Nygaard I. Adult conservative management. In: Abrams P, Cardoza L, Khoury S, Wein A editor(s). Incontinence: 3rd International Consultation on Incontinence. Plymouth: Health Publications, 2005:5-964.

### Zigmond 1983

Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatrica Scandinavica* 1983;**67**(6):361-70. [MEDLINE: 83279108]

## CHARACTERISTICS OF STUDIES

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

Fynes 1999	
Methods	Randomised controlled trial. Allocation: randomised (computer generated using Ran List) to vaginal biofeedback or anal biofeed- back augmented by electrical stimulation. Blinding: therapist blind to obstetric history and previous test findings. Outcome assessor blind to treatment group. Follow-up: 12 weeks treatment. Setting: single centre, Dublin, Ireland. Withdrawals: one. Intention to treat: no.



Fynes 1999 (Continued)	Exclusion criteria: none stated.			
Participants	Sample: 40 consecutive women with faecal incontinence caused by obstetric trauma presenting to a dedicated perineal clinic. Age range 18-48 years (mean 32 years). Mean duration of symptoms 4 months (range 3-28 months). 37 symptomatic after primary repair of recognised anal sphincter disruption; 3 traumatic instrumental delivery with no attempt at repair. 24 were primiparous, 16 were multiparous. No significant differences between the 2 groups in age, parity or duration of symptoms.			
Interventions	Sensory biofeedback: b minute sessions for 12 seconds relaxation bet Augmented biofeedbac puter with anal probe t al position. 13-second o seconds, fast twitch: 3 f 20Hz for 10 minutes (5 stimulation with 30 sec Both groups advised to ed).	by continence nurse using Peritron perineometer vaginal probe. Weekly 30 weeks. Fast twitch: aim for 20 short maximum contractions of 6-8 seconds, 10 ween. Slow twitch: aim for 30 seconds duration. Patients treated supine. ck: weekly sessions with a specialist physiotherapist using Incare PRS 9300 com- o give audiovisual EMG feedback and electrical stimulation. Patient in left later- cycles: 5 seconds activity, 8 seconds rest, for 15 minutes. Slow twitch: hold for 5 fast contraction in 5 seconds, alternating. Then electrical stimulation, 20% ramp: seconds stimulation, 8 seconds rest); then 50Hz, time unspecified, 8 seconds conds rest.		
Outcomes	Anorectal manometric symmetry index), symp	parameters (resting, squeeze and squeeze increment pressures and a vector otom questionnaire and continence scores.		
Notes	Compared two completely different interventions. The authors' claim that the difference in outcome is attributable to electrical stimulation is question- able.			
Risk of bias				
Bias	Authors' judgement	Support for judgement		
Allocation concealment?	Low risk	A - Adequate		

# Mahony 2004

Methods	Randomised controlled trial. Allocation: computer generated allocations in ratio of 1:1, contained in sealed opaque envelopes. Blinding: Physiotherapist blinded to patient's manometry and ultrasound results. Outcome assessor blinded to individual treatment protocol. Follow-up: 12 weeks treatment. Setting: Perineal Clinic, National Maternity Hospital, Dublin, Ireland. Withdrawals: Four women biofeedback alone, two women biofeedback with electrical stimulation Intention to treat: no Inclusion criteria: symptoms of impaired faecal incontinence after obstetric injury Exclusion criteria: History of diabetes mellitus, inflammatory bowel disease, previous anorectal surgery, or malignancy
Participants	Sample: 60 consecutive women with faecal incontinence caused by obstetric trauma presenting to a dedicated perineal clinic. Median age: 35 years (range 23 to 39). Median parity: one (range 1 to 3) Groups comparable as regards mode of delivery, duration of symptoms
Interventions	Standard intra-anal electromyographic biofeedback training of the pelvic floor or intra-anal elec- tromyographic biofeedback with electrical stimulation of anal sphincter weekly for 12 weeks. Both in- terventions performed with an Incare PRS 9400 system connected to 17 inch television monitor and

Electrical stimulation for faecal incontinence in adults (Review)



#### Mahony 2004 (Continued)

endoanal probe. Slow twitch exercises alternated with fast twitch exercises. Electrical stimulation performed with standard frequency of 35 Hz with 20% ramp modulation time. Stimulation was performed for 20 mins with 5 secs stimulation and 8 secs relaxation between contractions. All patients performed standard Kegel exercises daily

Outcomes	Anorectal manometry, bowel function questionnaire		
Notes			
Risk of bias			
Bias	Authors' judgement	Support for judgement	
Allocation concealment?	Low risk	A - Adequate	

#### Norton 2006a

Methods	Randomised controlled trial. Allocation: random numbers generated by Excel in advance placed in opaque brown envelopes. Blinding: Patient blinded, research nurse not blinded Follow-up: 8 weeks treatment. Setting: single centre, tertiary colorectal hospital, UK. Withdrawals: 20/90 did not complete. Intention to treat: yes Inclusion criteria: biofeedback referrals. Exclusion criteria: patients refused informed consent, under 18 years, pregnant females or within six weeks of delivery, history of pelvic malignancy, active inflammatory bowel disease, active perianal sep- sis, painful haemorrhoids or fissure, previous experience of using an electric stimulator to treat urinary or faecal incontinence		
Participants	Sample: 90 patients referred for biofeedback for faecal incontinence in a tertiary referral hospital and on waiting list for biofeedback treatment, were contacted by telephone or mail by a research nurse and offered option of electric stimulation while awaiting their first consultation. Those expressing a willingness to participate were sent an information booklet, a bowel symptom questionnaire and one-week bowel di- ary, and given an appointment to attend the hospital for a single consultation with the research nurse. Those attending with a completed diary and questionnaire were asked to sign a consent form to enter the study		
Interventions			
Outcomes	one week bowel diary,	symptom questionnaire, manometry, patient assessment of outcome	
Notes			
Risk of bias			
Bias	Authors' judgement	Support for judgement	
Allocation concealment?	Low risk	A - Adequate	

#### **Osterberg 2004**

Methods Randomised controlled trial. Electrical stimulation for faecal incontinence in adults (Review)



Osterberg 2004 (Continued)		
	son who did not partici resting pressure to ach Blinding: states randon	pate in the study. Stratified on the basis of the difference between squeeze and ieve similar level of external anal sphincter incompetence in each group. nisation by an "independent person".
	Follow-up: patients eva	aluated 3, 12 and 24 months after completion of treatment
	Setting: single centre, l	Jniversity Hospital, Uppsala, Sweden.
	Intention to treat: no	surgery group , three from electrostimulation group
	Inclusion criteria: patie incontinence persists a	nts referred over three year period with disabling faecal incontinence and fter dietary advice had been given and standardized treatment with bulking t least two months
	Exclusion criteria: Patie	ents with endosonographic anal sphincter defect, rectal prolapse or intra-anal
	intussusception, previo	ous anorectal surgery other than haemorrhoidectomy
Participants	Sample: 70 patients. 35 Age: Levatorplasty 68 n Sex ratio M:F (complete no difference between	5 randomised to anterior levatorplasty, 35 to anal plug electrostimulation nedian (52-80), electrostimulation 64 median (43-81) ers) 2:29 levatorplasty, 5:23 electro stimulation groups as regards parity and sex ratio
Interventions	Anterior levatorplasty i the rectum, with expos Two layers of 0/0 non-a nal sphincter was mob cm high. In contrast to scribed by Parks.	nvolved dissection between the posterior wall of the vagina and anterior wall of ure of the puborectal and pubococcygeal muscles on either side of the midline. Ibsorbable sutures were used to approximate the levator ani muscles. The exter- ilized and plicated with four to six absorbable sutures, giving a perineal body 2-3 all women, two men in the levatorplasty group underwent postanal repair as de-
	The pelvic floor stimula anal (in women also a w with two controls, by w stimulation frequency were lubricated with an varying current just bel ment lasted for 20 min, treated by the same the	ator MS210 (Medicon, Trondheim, Norway) consists of a pulse generator with an vaginal) plastic plug with attached electrodes. The pulse generator is supplied which the energy delivered and the frequency of stimulation can be varied. The was 25 Hz and the duration 1.5 s, with a pulse-train interval of 3 s. The electrodes in electrically conductive cream and introduced into the anal canal and vagina. A ow the sensation of burning or pain was given for maximum effect. Each treat- , and a total of 12 sessions were administered over 4-5 weeks. All patients were erapist.
Outcomes	validated questionnair anorectal manometry a	e and manovolumetry
Notes		
Risk of bias		
Bias	Authors' judgement	Support for judgement
	······	
Allocation concealment?	Low risk	A - Adequate

# Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
George 1991	Non-randomised. Abstract comparing one type of stimulation on a gracilis neosphincter (continuous low frequen- cy 2Hz, no=6) to another (intermittent high frequency 15-25Hz, no=6). The information present- ed in the abstract is unclear, but suggests that both types of stimulation result in transformation to a slow twitch muscle but that the higher frequency may enhance neosphincter function and re-

Study	Reason for exclusion			
	duce the need for a de functioning stoma. Correspondence from one of the authors (Williams NS 2/12/99) confirmed that the study was non-randomised.			
Sprakel 1998	Non-randomised. Study of 45 patients with faecal incontinence (38 females, 7 males). 27 were idiopathic (the trans- lation for the German expression used is "insufficient pelvic floor") and 18 had trauma of the anal sphincter (caused by surgery or vaginal delivery). These were treated by pelvic floor exercises (x3/ day for 5-10 minutes) and transanal electrical stimulation "according to Wienert". There was no in- dication of the length of treatment. There was a control group of 29 patients (25 females, 4 males) who were treated with pelvic floor exercises alone. 14 were idiopathic and 15 had trauma of the anal sphincter. These were non-ran- domised and both the study and control group contained a variety of anal pathology other than "poor muscle function" (e.g. rectal prolapse, haemorrhoids, solitary rectal ulcer, perineal descent ) and had a variety of anal operations (such as haemorrhoidectomy, fistulectomy and fissurectomy). The authors concluded that electrostimulation and pelvic floor exercise is better than pelvic floor exercise alone in terms of the modified continence score of Holschneider. The results are similar for those with idiopathic incontinence and traumatic incontinence.			
Surh 1998	Translation obtained, not clear how patients allocated. Written to authors.			
Williams 1991	Non-randomised. Comparative study of an electrically stimulated neosphincter on 20 incontinent patients with a de- ficient anal sphincter and 12 patients in whom the anorectum had been excised or was congenital- ly absent.			

# Characteristics of ongoing studies [ordered by study ID]

Stott	
Trial name or title	A study to determine the effects of neuro-stimulation on anal sphincter function when used in con- junction with biofeedback and pelvic floor exercises in the treatment of faecal incontinence
Methods	
Participants	50 patients with faecal incontinence - referred to a nurse-led clinic - randomised by computer into two groups
Interventions	All will attend 12x 45 minute clinic sessions within a six month period.
	Both groups will receive the same instructions about pelvic floor exercises and will have the same duration biofeedback therapy at each clinic session
	One group will also receive a session of 30 Hz intra-anal electrical stimulation at each clinic session. The other group will have the same contact time with the therapist but will receive no stimulation.
Outcomes	Continence score, validated quality of life questionnaire, anal manometry, endoanal ultrasound.
Starting date	January 2000.
Contact information	Sonia Stott (tel. +44 161 276 1234 bleep 2775).
Notes	



# DATA AND ANALYSES

# Comparison 1. ELECTRICAL STIMULATION versus NO TREATMENT

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
1 Number of people failing to achieve full continence (worse, un- changed or improved)	0	0	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
2 Number of people with no im- provement in incontinence status (worse or unchanged)	0	0	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
3 Number of people dissatisfied with the treatment	0	0	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
4 Number of incontinence episodes per week	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
5 Number of pad changes required per week	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
6 Incontinence score	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
7 Number of people with adverse ef- fects	0	0	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
8 Sensory threshold (rectal balloon distension - ml)	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
9 Manometric resting pressure (cm of water)	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
10 Manometric squeeze pressure (cm of water)	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
11 Manometric squeeze increment (cm of water)	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
12 Duration of squeeze (seconds)	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
13 Vector symmetry index	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
14 Saline retention test (ml)	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
15 General health measures	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]

Electrical stimulation for faecal incontinence in adults (Review)



Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
16 Condition specific quality of life measures	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
17 Psychological health measures	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
18 Activities of daily living measures	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]

# Comparison 2. ELECTRICAL STIMULATION versus ANY OTHER TREATMENT

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
1 Number of people failing to achieve full continence (worse, un- changed or improved)	0	0	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
2 Number of people with no im- provement in incontinence status (worse or unchanged)	1	59	Risk Ratio (M-H, Fixed, 95% CI)	1.99 [0.76, 5.24]
3 Number of people dissatisfied with the treatment	0	0	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
4 Number of incontinence episodes per week	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
5 Number of pad changes required per week	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
6 Incontinence score	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
7 Number of people with adverse ef- fects	0	0	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
8 Sensory threshold (rectal balloon distension - ml)	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
9 Manometric resting pressure (cm of water)	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
10 Manometric squeeze pressure (cm of water)	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
11 Manometric squeeze increment (cm of water)	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
12 Duration of squeeze (seconds)	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]

Electrical stimulation for faecal incontinence in adults (Review)



Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
13 Vector symmetry index	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
14 Saline retention test (ml)	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
15 General health measures	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
16 Condition specific quality of life measures	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
17 Psychological health measures	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
18 Activities of daily living measures	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]

# Analysis 2.2. Comparison 2 ELECTRICAL STIMULATION versus ANY OTHER TREATMENT, Outcome 2 Number of people with no improvement in incontinence status (worse or unchanged).

Study or subgroup	Treatment	Control			Ri	sk Rat	io			Weight	<b>Risk Ratio</b>
	n/N	n/N			M-H, F	ixed, 9	95% CI				M-H, Fixed, 95% Cl
Osterberg 2004	9/28	5/31					-			100%	1.99[0.76,5.24]
Total (95% CI)	28	31								100%	1.99[0.76,5.24]
Total events: 9 (Treatment), 5 (Control)	1										
Heterogeneity: Not applicable											
Test for overall effect: Z=1.4(P=0.16)											
		Favours treatment	0.1	0.2	0.5	1	2	5	10	Favours control	

# Comparison 3. ELECTRICAL STIMULATION AS AN ADJUNCT versus ELECTRICAL STIMULATION ALONE

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
1 Number of people failing to achieve full continence (worse, un- changed or improved)	0	0	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
2 Number of people with no im- provement in incontinence status (worse or unchanged)	0	0	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
3 Number of people dissatisfied with the treatment	0	0	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
4 Number of incontinence episodes per week	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]

Electrical stimulation for faecal incontinence in adults (Review)



Cochrane Database of Systematic Reviews

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
5 Number of pad changes required per week	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
6 Incontinence score	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
7 Number of people with adverse ef- fects	0	0	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
8 Sensory threshold (rectal balloon distension - ml)	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
9 Manometric resting pressure (cm of water)	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
10 Manometric squeeze pressure (cm of water)	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
11 Manometric squeeze increment (cm of water)	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
12 Duration of squeeze (seconds)	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
13 Vector symmetry index	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
14 Saline retention test (ml)	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
15 General health measures	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
16 Condition specific quality of life measures	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
17 Psychological health measures	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
18 Activities of daily living measures	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]

# Comparison 4. ELECTRICAL STIMULATION AS AN ADJUNCT versus ANY OTHER TREATMENT

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
1 Number of people failing to achieve full continence (worse, unchanged or improved)	2		Risk Ratio (M-H, Fixed, 95% CI)	Totals not select- ed



Cochrane Database of Systematic Reviews

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
2 Number of people with no improve- ment in incontinence status (worse or unchanged)	2		Risk Ratio (M-H, Fixed, 95% CI)	Totals not select- ed
3 Number of people dissatisfied with the treatment	0	0	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
4 Number of incontinence episodes per week	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
5 Number of pad changes required per week	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
6 Incontinence score	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
7 Number of people with adverse ef- fects	0	0	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
8 Sensory threshold (rectal balloon distension - ml)	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
9 Manometric resting pressure (cm of water)	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
10 Manometric squeeze pressure (cm of water)	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
11 Manometric squeeze increment (cm of water)	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
12 Duration of squeeze (seconds)	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
13 Vector symmetry index	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
14 Saline retention test (ml)	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
15 General health measures	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
16 Condition specific quality of life measures	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
17 Psychological health measures	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
18 Activities of daily living measures	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]

Electrical stimulation for faecal incontinence in adults (Review)

# Analysis 4.1. Comparison 4 ELECTRICAL STIMULATION AS AN ADJUNCT versus ANY OTHER TREATMENT, Outcome 1 Number of people failing to achieve full continence (worse, unchanged or improved).

Study or subgroup	Treatment	Control		Risk	Ratio		<b>Risk Ratio</b>
	n/N	n/N		M-H, Fixe	d, 95% CI		M-H, Fixed, 95% Cl
Fynes 1999	5/20	12/19					0.4[0.17,0.91]
Mahony 2004	20/28	20/26	1	-	_		0.93[0.68,1.27]
		Favours treatment	0.01	0.1	L 10	0 100	Favours control

# Analysis 4.2. Comparison 4 ELECTRICAL STIMULATION AS AN ADJUNCT versus ANY OTHER TREATMENT, Outcome 2 Number of people with no improvement in incontinence status (worse or unchanged).

Study or subgroup	Treatment	Control	Risk Ratio				<b>Risk Ratio</b>
	n/N	n/N	М-Н, І	ixed, 95	5% CI		M-H, Fixed, 95% CI
Fynes 1999	0/20	8/19	·	_			0.06[0,0.91]
Mahony 2004	5/28	3/26	-				1.55[0.41,5.84]
		Favours treatment	0.01 0.1	1	10	100	Favours control

# Comparison 5. ONE MODALITY OF ELECTRICAL STIMULATION versus ANY OTHER MODALITIES OF ELECTRICAL STIMULATION

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
1 Number of people failing to achieve full continence (worse, un- changed or improved)	0	0	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
2 Number of people with no im- provement in incontinence status (worse or unchanged)	0	0	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
3 Number of people dissatisfied with the treatment	0	0	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
4 Number of incontinence episodes per week	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
5 Number of pad changes required per week	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
6 Incontinence score	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
7 Number of people with adverse ef- fects	0	0	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
8 Sensory threshold (rectal balloon distension - ml)	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
9 Manometric resting pressure (cm of water)	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]

Electrical stimulation for faecal incontinence in adults (Review)



Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
10 Manometric squeeze pressure (cm of water)	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
11 Manometric squeeze increment (cm of water)	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
12 Duration of squeeze (seconds)	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
13 Vector symmetry index	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
14 Saline retention test (ml)	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
15 General health measures	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
16 Condition specific quality of life measures	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
17 Psychological health measures	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
18 Activities of daily living measures	0	0	Mean Difference (IV, Fixed, 95% Cl)	0.0 [0.0, 0.0]

# APPENDICES

# Appendix 1. Search methods used for a previous version of this review

For an earlier version of this review extra specific searches were performed. These are detailed below. The following electronic bibliographic databases were searched: CENTRAL - dates searched: Issue 4, 1999; MEDLINE on PubMed - dates searched: 1966 to November 1999; EMBASE on Ovid via BIDS - dates searched: January 1998 to October 1999. The following search terms were used in each database (no limits were applied to the searches): Fecal incontinence/; ((faecal or fecal) and incontinen\$).tw.

We searched the reference lists of relevant articles for other possible relevant trials.

We did not impose any language or other limits on the searches.

# WHAT'S NEW

Date	Event	Description
9 October 2008	Amended	Converted to new review format.

# HISTORY

Protocol first published: Issue 4, 1998 Review first published: Issue 2, 2000



Date	Event	Description
18 May 2007	New citation required and conclusions have changed	Substantive amendment Three studies added, Mahoney 2004, Norton 2006a, Osterberg 2004

## **CONTRIBUTIONS OF AUTHORS**

One reviewer (G. Hosker) wrote the initial protocol of the review. All three reviewers independently assessed the relevance and quality of eligible studies and selected which to include in the review. Three reviewers (G. Hosker, C. Norton, J. Cody) independently extracted data from trial reports of identified studies. All three reviewers interpreted the results and contributed to the writing of the final version of the review.

#### DECLARATIONS OF INTEREST

None

# SOURCES OF SUPPORT

#### **Internal sources**

• Chief Scientist Office, Scottish Executive Health Department, UK.

#### **External sources**

• National Health Service R&D Programme for People with Physical and Complex Disabilities, UK.

#### INDEX TERMS

#### Medical Subject Headings (MeSH)

\*Electric Stimulation Therapy; Biofeedback, Psychology; Fecal Incontinence [\*therapy]; Randomized Controlled Trials as Topic

#### **MeSH check words**

Adult; Humans