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[Intervention Review]

Biofeedback and/or sphincter exercises for the treatment of faecal incontinence in adults

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ABSTRACT

Background

Faecal incontinence is a particularly embarrassing and distressing condition with significant medical, social and economic implications. Anal sphincter exercises (pelvic floor muscle training) and biofeedback therapy have been used to treat the symptoms of people with 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 biofeedback and/or anal sphincter exercises/pelvic floor muscle training for the treatment of faecal incontinence in adults.

Search methods

We searched the Cochrane Incontinence Group Specialised Trials Register (searched 24 January 2012) which contains trials from searching CENTRAL, MEDLINE and handsearching of conference proceedings; and the reference lists of relevant articles.

Selection criteria

All randomised or quasi-randomised trials evaluating biofeedback and/or anal sphincter exercises in adults with faecal incontinence.

Data collection and analysis

Two review authors assessed the risk of bias of eligible trials and two review authors independently extracted data from the included trials. A wide range of outcome measures were considered.

Main results

Twenty one eligible studies were identified with a total of 1525 participants. About half of the trials had low risk of bias for randomisation and allocation concealment.

One small trial showed that biofeedback plus exercises was better than exercises alone (RR for failing to achieve full continence 0.70, 95% CI 0.52 to 0.94).

One small trial showed that adding biofeedback to electrical stimulation was better than electrical stimulation alone (RR for failing to achieve full continence 0.47, 95% CI 0.33 to 0.65).

The combined data of two trials showed that the number of people failing to achieve full continence was significantly lower when electrical stimulation was added to biofeedback compared against biofeedback alone (RR 0.60, 95% CI 0.46 to 0.78).

Sacral nerve stimulation was better than conservative management which included biofeedback and PFMT (at 12 months the incontinence episodes were significantly fewer with sacral nerve stimulation (MD 6.30, 95% CI 2.26 to 10.34).

There was not enough evidence as to whether there was a difference in outcome between any method of biofeedback or exercises. There are suggestions that rectal volume discrimination training improves continence more than sham training. Further conclusions are not warranted from the available data.

Authors' conclusions

The limited number of identified trials together with methodological weaknesses of many do not allow a definitive assessment of the role of anal sphincter exercises and biofeedback therapy in the management of people with faecal incontinence. We found some evidence that biofeedback and electrical stimulation may enhance the outcome of treatment compared to electrical stimulation alone or exercises alone. Exercises appear to be less effective than an implanted sacral nerve stimulator. While there is a suggestion that some elements of biofeedback therapy and sphincter exercises may have a therapeutic effect, this is not certain. Larger well-designed trials are needed to enable safe conclusions.

PLAIN LANGUAGE SUMMARY

Exercises of the muscles around the anus with or without biofeedback (aids for knowing when the muscles are contracting) for the treatment of faecal incontinence in adults

Faecal incontinence (inability to control bowel movements or leaking stool) can be a very embarrassing and socially restricting problem. There are many possible causes, including childbirth damage to the muscles which control bowel movements. Exercises to strengthen these muscles and 'biofeedback', where equipment is used to show people how to use the muscles properly, are often recommended. There was some evidence from trials suggesting that these treatments are helpful. If patients who have tried and failed other simpler treatments, such as changing their diet or using medications, are selected then biofeedback using computer equipment or rectal balloon is more beneficial than exercises alone. Exercises and electrical stimulation used in the anus may be more helpful than vaginal exercises for women with faecal incontinence after childbirth. About half of the 21 trials were at low risk of bias. They compared different combinations of treatments and different outcome measures, making comparison between them difficult. However, a small number of the larger recent trials provide better evidence.

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 2009).

Faecal incontinence is a common healthcare problem, affecting 5% to 10% of community-dwelling adults (Macmillan 2004; Perry 2002; Whitehead 2009), 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 (Boreham 2005; Cotterill 2011; Wilson 2007), with severe social restrictions in many instances (Rockwood 1999; Rockwood 2000).

Faecal incontinence has many possible causes, including (among others) obstetric or other trauma, or a congenital abnormality of one or both of the anal sphincters or the pelvic floor muscles; 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 affecting toilet habits. For many people, a combination of structural, physiological and psycho-social factors (Norton 2004; Rao 2004; Tuteja 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 loose stool or intestinal hurry; or of passive soiling in the absence of an urge to defecate, 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 the treatment options are limited, relying mainly on surgery and constipating drugs (Madoff 2009; Norton 2009; Whitehead 2001).

Description of the intervention and how it might work

Pelvic floor muscle training (PFMT) is a well-established therapy for the treatment of urinary incontinence (Dumoulin 2010), 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 and training techniques. The role of the ano-rectal angle, maintained by the pubo-rectalis muscle, is controversial but is believed to be important in faecal continence. It is not established whether pelvic floor muscle training can be distinguished from anal sphincter exercises in practice by patients, and the two will be considered together for the purposes of this review, with the use of vaginal or anal palpation, teaching, or biofeedback made explicit. The purpose of the exercises is stated variously as enhancing the strength, speed, or endurance of voluntary anal sphincter contraction. Some have also suggested that there could be an effect on resting closure pressure of the anus. Reported exercise regimens for faecal incontinence vary widely in terms of the type, number and intensity of exercises taught (for example maximal squeeze and how long to attempt to hold it; submaximal endurance squeeze; fast twitch squeezes), how many per day and in what pattern, and in length of time the exercises are suggested to be performed for. Some have reported a single regimen for all patients (for example 10 squeezes of 5 seconds each five times per day); others have individualised the exercise programme, depending on the initial muscle strength and endurance, on the principle of improving muscle performance by 'overload' (aiming to exercise at a level just above current ability). There is no consensus among professionals on the best exercise regimen for faecal incontinence.

Biofeedback uses equipment to record or amplify and then feed back to the patient activities of the body. Originally based on the principles of operant conditioning (Engel 1974), it is a very commonly reported clinical treatment for faecal incontinence in the colorectal and gastroenterology literature. Reviews of large numbers of case series, in the era before randomised controlled trials became the accepted method for evaluating the efficacy of treatment, have concluded that biofeedback is an effective treatment for the majority of people with faecal incontinence (Heymen 2001: Norton 2001). Many different therapies have been used with people with faecal incontinence under the label of 'biofeedback'. Early studies concentrated on operant conditioning to enhance what was presumed to be a reflex contraction of the external anal sphincter in response to the reflex inhibition of the internal anal sphincter when the rectum filled (recto-anal inhibitory reflex). It has subsequently been suggested that this external sphincter reaction is in fact not a reflex but a voluntary response (Whitehead 1981). Other studies have focused on teaching the patient to discriminate progressively smaller volumes of distension of a rectal balloon, and to respond appropriately (by contracting the external sphincter) and as promptly as possible, abolishing any delay in sensation or reaction to it. Some have disregarded these elements and focused entirely on improving the strength or endurance of external anal sphincter contraction.

Three main modalities have been described

1. Rectal sensitivity training. A rectal balloon is gradually distended with air or water and the patient is asked to report the first sensation of rectal filling. Once this threshold volume is determined, repeated re-inflations of the balloon are performed with the objective being to teach the patient to feel the distension at progressively lower volumes. The rationale is that some patients are found to have high threshold volumes and if the patient detects stool arriving sooner there is more possibility to either find a toilet or use an anal squeeze, or both. Conversely, the same technique can also be used to teach the patient to tolerate progressively larger volumes, in those with urgency and a hypersensitive rectum.

2. Strength training. Biofeedback techniques have been used to demonstrate to the patient anal sphincter pressures or activity, thereby enabling teaching of anal sphincter exercises and giving feedback on performance and progress. This can be achieved by using electromyography (EMG) skin electrodes, manometric pressures, intra-anal EMG, or anal ultrasound. The patient is encouraged by seeing or hearing the signal to enhance squeeze strength and endurance. There is no consensus on an optimum exercise regimen for use at home between sessions, nor on the number of squeezes, the frequency of exercises or

treatment duration, with different authors describing very different programmes.

3. Co-ordination training. Some authors have described a three-balloon system for biofeedback for faecal incontinence. One distension balloon is situated in the rectum, the second and third smaller pressure-recording balloons are situated in the upper and lower anal canal. Rectal distension triggers the rectal-anal inhibitory reflex. This momentary anal relaxation is a point of vulnerability for people with faecal incontinence and incontinence can occur at this time. By distending the rectal balloon and showing the patient this consequent pressure drop, the aim is to teach the patient to counteract this by a voluntary anal squeeze that is hard enough and for long enough for resting pressure to return to its baseline level.

The three methods are not mutually exclusive, and many protocols combine two or three elements together. There has been considerable variation in protocols, such as the number or frequency of sessions, intensity and duration of exercises and instructions for practice at home. Some studies have included other elements, such as patient teaching, diet and fluid advice and titration of medication, although many fail to mention these other elements or give details. Some have used additional surface electrode electrical stimulation of the anal sphincter muscles, which is the subject of a separate Cochrane review (Hosker 2007). There is widespread agreement on the crucial role of patient motivation and the patient-therapist interaction.

Why it is important to do this review

There are numerous case series reporting on biofeedback for faecal incontinence, nearly all of which have reported positive results (Heymen 2001; Norton 2001). Only one published study has reported negative results (van Tets 1996). It would be easy to conclude from case series that biofeedback or exercises are an effective intervention. However, it is known that there is a publication bias in favour of publishing positive results and that there is an effect of intervention per se, especially in many functional gastrointestinal disorders (Thompson 1999). Delivering a programme of biofeedback or anal sphincter exercises, or both, inevitably involves a complex combination of patient-therapist interaction, patient education and formal or informal advice on a range of related issues. Randomised controlled trials provide the best evidence of the efficacy of health care interventions. More complex interventions are likely to involve more clinic attendances for the patients and more costs. Patients who fail to respond to conservative treatments are often referred for costly surgical treatments such as sacral nerve stimulation. If they have not tried the most effective available conservative interventions, they may undergo surgery unnecessarily or alternatively decide to live with distressing symptoms which might have responded to the best available treatment.

The aim of the present review is to systematically search for and combine evidence from all relevant randomised controlled trials on the effects of biofeedback or sphincter exercises, or both, for the treatment of faecal incontinence in order to provide the best evidence currently available on which to base recommendations for clinical practice and for future research.

OBJECTIVES

To determine the effectiveness of anal sphincter exercises/pelvic floor muscle training (PFMT) with or without biofeedback in the treatment of the symptoms of faecal incontinence in adults. The following comparisons were considered:

1. Anal sphincter exercises/PFMT with or without biofeedback versus no treatment

2. Anal sphincter exercises/PFMT with or without biofeedback versus any other treatment alone

3. Anal sphincter exercises/PFMT with or without biofeedback and another treatment versus any other treatment alone

4. Anal sphincter exercises/PFMT with or without biofeedback and another treatment versus exercises with or without biofeedback

5. Anal sphincter exercises/PFMT and biofeedback versus anal sphincter exercises/PFMT alone

6. One type of biofeedback versus another type of biofeedback

7. One type of anal sphincter exercises/PFMT versus another type of anal sphincter exercises/ PFMT

METHODS

Criteria for considering studies for this review

Types of studies

All randomised or quasi-randomised controlled trials of patients with faecal incontinence receiving anal sphincter exercises or biofeedback, or both as treatment.

Types of participants

Adults (18 years and older or as defined by the trialists) suffering from faecal incontinence.

Types of interventions

Anal sphincter exercises and/or biofeedback.
Under the term 'anal sphincter exercises' we included: anal sphincter exercises, 'Kegel exercises' (Kegel 1948), pelvic floor exercises, or pelvic floor muscle training.

All types of visual, sensory (usually with a rectal balloon) or auditory biofeedback were considered. As the specific techniques used for biofeedback might have differed among studies, a clear description of the modality used was made explicit in each instance (see table 'Characteristics of included studies').

Types of outcome measures

1. Patient symptoms

Incontinence status
Frequency of incontinence
Number of pads changes
Incontinence score.
Occurrence of adverse events

Diary

2. Patient satisfaction with outcome

Self-report

3. Ano-rectal physiology measurements

Resting anal pressure (pressure or EMG)
Pressure rise and squeeze increment on voluntary contraction (pressure or EMG)
Duration of pressure rise on voluntary contraction (pressure or EMG)
Vector Symmetry Index
Rectal sensation assessment (by balloon distention or electrical means, or both)

4. Health status measures

Psychological health measures (e.g. Hospital Anxiety and Depression Scale, HADS) (Zigmond 1983)

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

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

5. Health economics

Costs of interventions
Resource implications
Cost effectiveness or cost utility evaluation (e.g. cost per QALY) (Weinstein 1977)

6. Other outcomes

Other outcome measures given by authors and judged to be important when undertaking the review

Search methods for identification of studies

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

Electronic searches

This review has drawn on the search strategy developed by the Cochrane Incontinence Group. Relevant trials were identified from the Incontinence Group Specialised Trials Register, which is described under the Incontinence 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 date of the most recent search of the register was 24 January 2012.

The trials in the Incontinence Group Specialised Trials Register are also contained in CENTRAL. The Incontinence Group Trials Register was searched using the Group's own keyword system. The search terms used were:

({design.rct* or design.cct*})
AND
({TOPIC.FAECAL.INCON* or TOPIC.FAECAL.NEUROGENIC*})
AND
({INTVENT.PHYS.PFMT* or INTVENT.PHYS.BIOFEED* or INTVENT.PHYS.SphincterExercise* or INTVENT.PHYS.exercise*})

(All searches were of the keyword field of Reference Manager 12, ISI ResearchSoft).

Searching other resources

We checked all reference lists of identified trials.

Data collection and analysis

Trials selection

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

Risk of bias

The risk of bias of identified trials was assessed independently by the two review authors using the Cochrane Collaboration 'Risk of bias' tool (Higgins 2011a). This takes into account the quality of random sequence generation, 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.

Where the method of allocation concealment was not clearly reported the authors were contacted, if possible, for clarification.

Any disagreements were resolved by discussion. Studies were excluded if they not meet the pre-specified inclusion criteria. The list of excluded studies and the reasons for their exclusion are summarised in the table 'Characteristics of excluded studies'.

Data extraction

Data extraction from the included studies was undertaken independently by the review authors. Only published data have been used for the purposes of this review. Data were processed as described in the Cochrane Collaboration Handbook (Higgins 2011b). Any difference of opinion was resolved by discussion.

Missing information was sought from trialists, if necessary.

Analysis

Data were analysed using Review Manager (RevMan) software.

For each trial, risk ratios and 95% confidence intervals were calculated for dichotomous outcomes using a fixed-effect model. Continuous variables were processed using mean and standard deviation values. Where the results were reported in terms of the mean and standard error of the mean (SEM), the standard deviation (SD) was calculated using the standard statistical equation: SD = SEM x square root (sample size). 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 risk ratios less than one or a WMD less than zero indicated a reduction in unfavourable events (that is 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

Results of the search

Three hundred and ten possible studies were identified by the search of which 21 are included in the review. The flow of literature through the assessment process is shown in the PRISMA flowchart (Figure 1).

Figure 1. PRISMA study flow diagram.

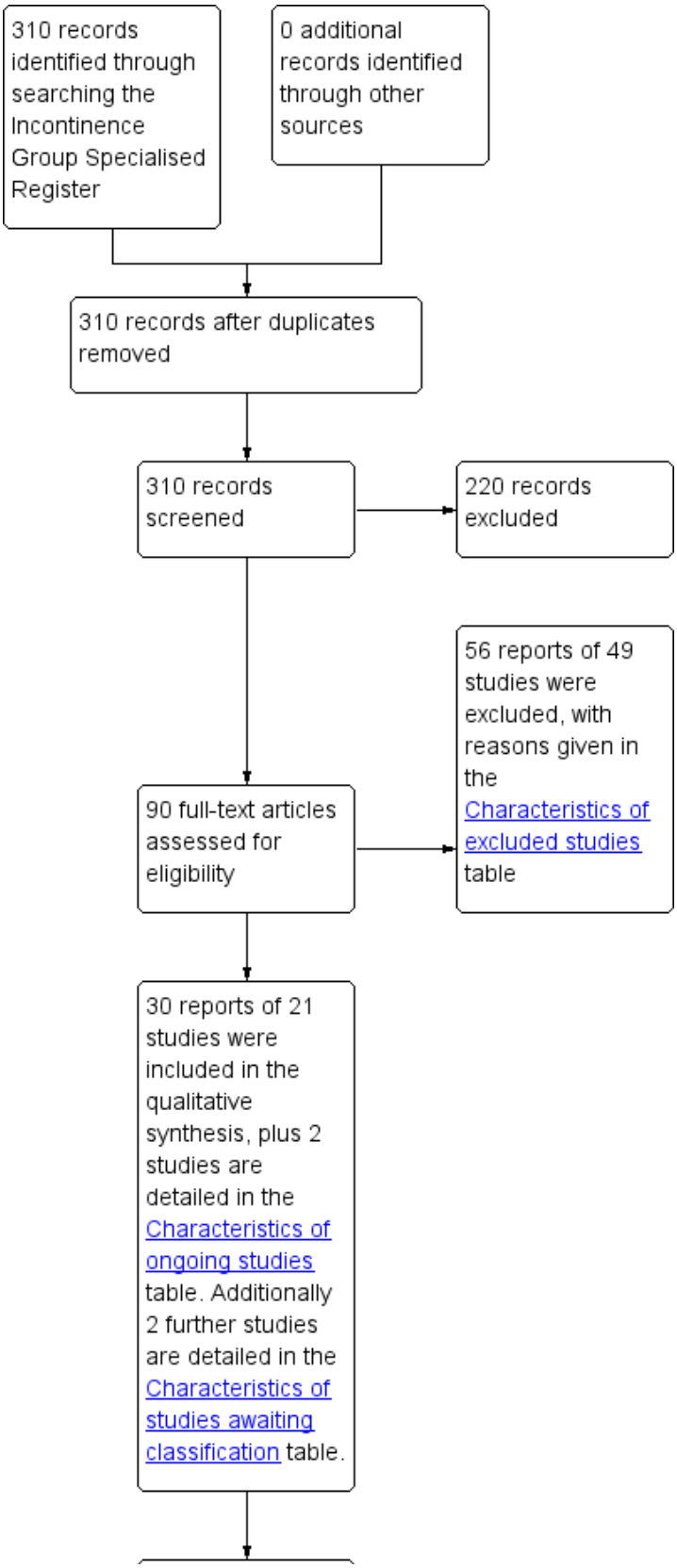
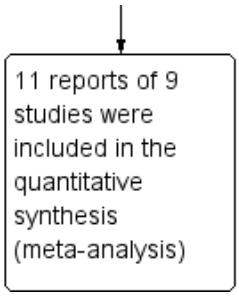


Figure 1. (Continued)



Included studies

Twenty one studies are included in this review (Bartlett 2011; Bols 2011; Davis 2004; Fynes 1999; Healy 2006; Heymen 2000; Heymen 2009; Hinninghofen 2003; Ilnyckyj 2005; Latimer 1984; Mahony 2004; Markwell 2006; McHugh 1986; Miner 1990; Naimy 2007; Norton 2003; Schwandner 2010; Schwandner 2011; Solomon 2003; Tjandra 2008; Whitehead 1985). A total of 1525 participants were randomised.

Further details can be found in the Table of Characteristics of included studies.

Design

One study (Whitehead 1985) allocated alternate patients to exercises or a control group.

Seventeen studies prospectively randomised patients to one of two (Bartlett 2011; Bols 2011; Davis 2004; Fynes 1999; Healy 2006; Heymen 2009; Ilnyckyj 2005; Mahony 2004; Markwell 2006; Naimy 2007; Schwandner 2010; Schwandner 2011; Tjandra 2008), three (Hinninghofen 2003; Solomon 2003) or four groups (Heymen 2000; Norton 2003).

Two trials (Latimer 1984; Miner 1990) which attempted to evaluate different components of biofeedback therapy had a complex design. One trial (Latimer 1984) reported the results of single case experiments employed with eight incontinent patients randomly allocated to different components of biofeedback (A, B, C or D). The single case designs were A B A C A D A or A C A B A D A. For each patient, results of the pre-treatment phase were compared to those of the last follow-up. Results at the end of each treatment phase were either not reported or provided in a form unsuitable for statistical analyses, rendering the interpretation of trial findings difficult. The other trial (Miner 1990), which investigated some of the factors thought to be responsible for the improvement of patients undergoing biofeedback therapy, was a 'two-phase randomised trial'. Patients were initially randomised to one of two groups for sensory retraining (phase II); before and after treatment results were reported for both intervention groups. At the end of phase I all patients were again randomly assigned to one of two groups for either strength or coordination training. After a month they were crossed over. Results of the cross-over phases were not clearly reported. Only results of the final assessment were given for phase II.

One trial randomised patients to two groups using a cross-over design (McHugh 1986).

Sample sizes

The sample sizes of included trials ranged from eight (Latimer 1984) to 171 (Norton 2003) participants.

Setting

Each of the trials, except two (Schwandner 2010; Schwandner 2011), were carried out in a single hospital centre; these were in a variety of countries. Schwandner 2010 was a multi centre trial which involved eight centres in Germany (Schwandner 2010).

Participants

In all studies where information on gender was reported, the majority of participants were female. Most studies enrolled patients with mixed aetiologies. Four studies included women with obstetric trauma only (Davis 2004; Fynes 1999; Mahony 2004; Naimy 2007). One study included older patients only (Whitehead 1985). One study included only patients undergoing surgical anal sphincter repair (Davis 2004). Some investigators only included patients who had failed previous dietary and medication interventions (Bols 2011; Heymen 2009). In some studies patients with specific diagnoses such as rectal prolapse were excluded, inflammatory bowel disease, and irritable bowel syndrome (see table 'Characteristics of included studies' for details of the inclusion and exclusion criteria in each study).

Interventions

One study used a dual-balloon system with visual or auditory feedback of anal pressure. Patients were encouraged to contract the anal sphincter in response to rectal distension. Exercises during the session (one hour per week for six weeks, commenced three months following anal sphincter repair surgery) and home practice included maximal, submaximal and fast-twitch contractions practised at least twice daily. The control group had no therapist contact, biofeedback or exercises (Davis 2004). Another study compared rectal balloon therapy with PFMT against PFMT alone (Bols 2011).

Two other studies included a no biofeedback or exercises group. In one of these studies the control group received one-to-one time and advice (Norton 2003); in the other study the control group received no intervention (Whitehead 1985). Three studies included a no-biofeedback exercise group which involved exercises taught digitally (Norton 2003; Solomon 2003) or verbally (Ilnyckyj 2005).

Heyman 2009 compared manometric biofeedback and pelvic floor exercises against exercises alone.

Bartlett compared a standard clinical protocol (sustained submaximal anal and pelvic floor exercises versus an alternative group (rapid squeeze plus sustained submaximal exercises) with biofeedback in both arms of the study. There were five outpatient sessions over eight weeks. The first four sessions were weekly; participants then practised techniques for four weeks before returning for their final session (Bartlett 2011).

Markwell (Markwell 2006) compared dietary modification, stool bulking agents, specific pelvic floor muscle action using abdominal muscles and defecation training compared with dietary modification, stool bulking agents and conventional pelvic floor exercises.

Tjandra (Tjandra 2008) compared optimum medical therapy, including pelvic floor exercises, bulking agents, dietary management of fluid and fibres, with a team of physiotherapists and dietitians. Attendance varied with need, usually monthly for six months then two-monthly. This group was compared against two phase sacral nerve stimulation: peripheral nerve evaluation for at least seven days; patients with a 50% reduction or more in incontinence episodes were surgically implanted with a permanent sacral nerve stimulator.

Two studies compared biofeedback and exercises against biofeedback, exercises and electrical stimulation (Fynes 1999; Mahony 2004). The Fynes study (Fynes 1999) randomised women with post-natal faecal incontinence to either vaginal pressure non-computer biofeedback (Peritron) with a nurse (weekly 30 minute sessions for 12 weeks) with fast and slow twitch exercises, or to computer-assisted anal probe EMG biofeedback (fast and slow twitch exercises) with a physiotherapist plus anal electrical stimulation at 20 Hz and 50 Hz. The Mahoney study (Mahony 2004) likewise recruited women with post-natal incontinence, randomised to have anal EMG biofeedback to perform fast and slow twitch contractions (10 minutes), with or without additional anal electrical stimulation at 35 Hz (20 minutes) at weekly sessions for 12 weeks. The Mahony study randomised women to intra-anal EMG biofeedback with or without anal electrical stimulation.

Schwandner 2010 (Schwandner 2010) compared "Triple target training" where amplitude-modulated middle-frequency electrical stimulation was combined with electromyography biofeedback and compared against electromyography biofeedback carried out at home daily for 20 minutes for a duration of nine months.

Schwandner 2011 (Schwandner 2011) compared "Triple target training" where amplitude-modulated middle-frequency electrical stimulation was combined with electromyography biofeedback and compared against low frequency electrostimulation.

Healy (Healy 2006) compared endo-anal pudendal nerve stimulation daily at home against attending a physiotherapy department for endo-anal electrical stimulation under supervision. They alternated biofeedback and electrical stimulation using augmented biofeedback.

Hinninghofen (Hinninghofen 2003) included three different groups, sphincter training compared with electrical stimulation, sphincter training with biofeedback and pelvic floor training without support; the intervention lasted three months.

Naimy (Naimy 2007) compared biofeedback with electrical stimulation. Biofeedback consisted of Neuro Trac ETS: using an Anuform anal probe. Quick 3 second squeeze; 10 second squeeze; squeeze for as long as it kept 50% of 3 second amplitude. Each squeeze was repeated five times with equal rest time between. The initial session was for 30 minutes with a 30 minute follow-up session one week later; then daily 30 minute sessions at home for eight weeks. Electrical stimulation consisted of Neuro Trac ETS: 30 or 40 Hz at alternate sessions; pulse width 200 µsec; upper limit 80 mAmp using Anuform anal probe. Patients turned up the stimulation to the maximum voltage which caused no discomfort: 3 seconds on then 3 seconds rest for 20 minutes twice daily at home. The initial session was 30 minutes with a 30 minute follow-up session one week later. Both interventions were carried out two times daily for eight weeks.

Four studies compared different methods of delivering biofeedback (Heymen 2000; McHugh 1986; Norton 2003; Solomon 2003). Heymen randomised patients to one of four groups:
1. anal EMG biofeedback plus home exercise;
2. anal EMG biofeedback plus rectal balloon distension sensory training to perceive lower rectal volumes and hold larger rectal volumes;
3. anal EMG biofeedback plus home exercise using a home biofeedback machine;
4. anal EMG biofeedback plus rectal balloon distension sensory training plus home exercise using a home biofeedback machine.

Norton (Norton 2003) randomised patients to one of four groups (all monthly 45 to 60 minute sessions for up to six sessions):
1. education, advice, urge resistance training, medication titration, diet and fluid adjustment (no biofeedback or exercise);
2. as 1, plus anal sphincter exercises taught by digital examination and a leaflet, with instruction to practise maximal, submaximal and fast-twitch exercises 10 times daily at home;
3. as 2. plus computer-assisted anal sphincter pressure biofeedback at each session;
4. as 3. plus a home anal EMG biofeedback machine for home practice.

Solomon (Solomon 2003) randomised patients to exercises taught digitally, via anal ultrasound biofeedback or via anal manometry biofeedback (five 30 minute sessions over four months).

One study compared clinic biofeedback with a home biofeedback device (McHugh 1986).

The design of the remaining two trials (Latimer 1984; Miner 1990), which attempted to evaluate different components of biofeedback therapy, have been described above.

Outcomes

Trials included a variety of outcome measures, many of which have not been validated.

Five trials reported patient evaluation of the outcome as a primary outcome measure (Bols 2011; Davis 2004; Naimy 2007; Norton 2003; Solomon 2003).

Eight studies used a patient-completed diary. One study took no episodes of faecal incontinence in a one week diary at the end of treatment as a 'complete response' (Ilnyckyj 2005).

Nine studies reported results of a variety of continence scores.

Eleven trials reported quality of life evaluation (Bartlett 2011; Bols 2011; Davis 2004; Healy 2006; Heymen 2009; Hinninghofen 2003; Mahony 2004; Naimy 2007; Norton 2003; Schwandner 2010; Tjandra 2008). One study used the SF-36 tool (Norton 2003).

Eight trials reported changes in manometric data as a proxy for patient outcome.

No attempts were made to include economic data in any trial.

See the Characteristics of included studies table for details of outcome measures used in each study.

Excluded studies

Of the excluded studies, some included children only, others were not randomised controlled trials (RCTs) or did not include the target interventions. Two were abstract reports of subsequently published full papers. See the table 'Characteristics of excluded studies' for details.

Risk of bias in included studies

Allocation

Thirteen trials (Bartlett 2011; Bols 2011; Davis 2004; Fynes 1999; Heymen 2000; Heymen 2009; Mahony 2004; Markwell 2006; Naimy 2007; Norton 2003; Schwandner 2010; Schwandner 2011; Solomon 2003) were judged to be at low risk of bias for random sequence generation, where an independent method such as a computer-generated list was used to produce the allocation of groups.

The quality of allocation concealment was judged to be adequate in 10 trials (Bartlett 2011; Bols 2011; Heymen 2009; Mahony 2004; Markwell 2006; Norton 2003; Schwandner 2010; Schwandner 2011; Solomon 2003; Tjandra 2008), unclear in 10 trials (Davis 2004; Fynes 1999; Healy 2006; Heymen 2000; Hinninghofen 2003; Ilnyckyj 2005; Latimer 1984; McHugh 1986; Miner 1990; Naimy 2007) and inadequate in one trial (Whitehead 1985). Most of the 'unclear' allocations mentioned computer-generated random numbers but did not explicitly state that allocation was concealed.

Blinding

In the Bartlett trial (Bartlett 2011) participants were blinded. Markwell (Markwell 2006) was described as 'single blind study' but information on who was actually blinded was not clearly reported.

In four trials (Bols 2011; Fynes 1999; Schwandner 2011; Solomon 2003) the outcome assessor was blind to patients' treatment protocol; in two trials outcome assessors were blinded for some of the outcomes (Norton 2003; Schwandner 2010).

In Heyman 2009 (Heymen 2009) the therapist telephoned to ask if participants had experienced 'adequate relief', which could be considered a violation of the trial protocol.

Incomplete outcome data

Most studies reported overall withdrawals with no indication of which groups patients were originally enrolled. Five trials (Bols 2011; Heymen 2009; Latimer 1984; Norton 2003; Schwandner 2010) that analysed data on an intention-to-treat basis and (Fynes 1999) had no or comparable drop outs from each group, were considered to be at low risk of bias.

In two trials (Latimer 1984; Miner 1990) data of the cross-over phases were not reported separately and it was not possible to analyse them as parallel group data.

Effects of interventions

Twenty one trials with a total of 1525 participants were included in this review.

Only nine trials (Davis 2004; Fynes 1999; Healy 2006; Heymen 2009; Miner 1990; Naimy 2007; Schwandner 2010; Schwandner 2011; Tjandra 2008) provided data in a form suitable for statistical analyses in RevMan.

Follow-up

Most studies reported results at the end of treatment or within a few weeks of completion only. Two studies reported results nine months after starting biofeedback (Davis 2004; Schwandner 2010) and five studies reported results one year after completing treatment (Bartlett 2011; Markwell 2006; Miner 1990; Norton 2003; Tjandra 2008).

1. Anal sphincter exercises/PFMT with or without biofeedback versus no treatment

One small cross-over trial with 25 participants was found (Miner 1990). Data suitable to be analysed were presented for the first phase of the trial only. In the experimental group active sensory retraining was employed to teach the patient to discriminate progressively smaller volumes of rectal balloon distension with decreasing delay. Controls received the same procedure but with no feedback on performance. Miner reported that sensory biofeedback produced better results than strength training alone. There was a significant difference between groups in incontinence episodes per week (MD -1.40, 95% CI -1.51 to -1.29) (Analysis 1.3) and rectal sensory threshold (WMD -12.90, 95% CI -14.10 to -11.70) (Analysis 1.8) favouring treatment. However, there was no statistically significant result for people failing to achieve full continence (RR 0.71, 95% CI 0.48 to 1.03) (Analysis 1.1) or no improvement in incontinence status (RR 0.26, 95% CI 0.07 to 1.03) (Analysis 1.2). Controls were said to achieve similar benefits when crossed over to active training but these data were not given.

2. Anal sphincter exercises/PFMT with or without biofeedback versus any other treatment alone

Biofeedback versus electrical stimulation

One trial (Naimy 2007) compared biofeedback with electrical stimulation alone, with no mention of exercises between treatments in either group. There was no statistically significant difference for numbers of people dissatisfied with treatment although the confidence interval was wide (Analysis 2.7).

3. Anal sphincter exercises/PFMT with or without biofeedback and another treatment versus any other treatment alone

Seven trials were found (Davis 2004; Healy 2006; Ilnyckyj 2005; Norton 2003; Schwandner 2011; Tjandra 2008; Whitehead 1985).

Exercises plus medical therapy versus sacral nerve stimulation

Tjandra compared optimal medical therapy, which consisted of pelvic floor exercises (biofeedback provided with digital guidance), bulking agents, dietary management of fluid and fibres versus

two phase sacral nerve stimulation (peripheral nerve evaluation for at least 7 days; patients with a 50% reduction or more in incontinence episodes were implanted with a permanent sacral nerve stimulator). At 12 months the number of incontinence episodes per week was significantly lower in the sacral nerve stimulation group (MD 6.30, 95% CI 2.26 to 10.34) (Analysis 3.4). However the difference in the number of pad changes per week was not statistically significant (Analysis 3.5). Both the Incontinence score and condition-specific quality of life (fecal incontinence quality of life index, FIQL) showed a statistically significant result favouring sacral nerve stimulation (MD 12.90, 95% CI 12.22 to 13.58, Analysis 3.6; MD 1.00, 95% CI 0.70 to 1.30, Analysis 3.16, respectively).

Exercises plus biofeedback plus surgery versus surgery alone

Davis (Davis 2004) compared anal sphincter repair with or without subsequent biofeedback commenced three months post-operatively in 38 women with obstetric-related anal sphincter injuries. There was no difference between the groups as regards continence score at nine months (Analysis 3.6) or patient satisfaction measured by visual analogue score (Analysis 3.19). Davis (Davis 2004) used a validated faecal incontinence quality of life questionnaire at nine months and there were no statistically significant differences between the groups in mean score changes for lifestyle, depression and embarrassment measurements.

Exercises plus biofeedback plus electrical stimulation versus electrical stimulation alone

Schwandner (Schwandner 2011) compared medium frequency electrical stimulation and electromyographic (EMG) biofeedback (known as triple target treatment) versus low frequency electrostimulation. electrostimulation. The number of people who failed to achieve full continence was significantly lower in the triple target group (RR 0.47, 95% CI 0.33 to 0.65, Analysis 3.1). The Wexner incontinence score was statistically significant favouring triple target training (MD -8.80, 95% CI -10.70 to -6.90) (Analysis 3.6).

Healy (Healy 2006) compared endo-anal pudendal nerve electrical stimulation daily at home versus endo-anal electrical stimulation plus augmented biofeedback under supervision and reported that low frequency endo-anal electrical stimulation significantly improves continence scores and quality of life. The data could not be analysed in RevMan.

Exercises plus biofeedback plus education versus exercises plus education

Ilnyckyj (Ilnyckyj 2005) compared anal sphincter exercises plus biofeedback plus education versus exercises and education in 23 women, the data were not suitable for further analyses in RevMan as no measures of variance were reported. Ilnyckyj reported that resting and squeeze manometric pressures were not significantly different between the groups, but there was a trend in favour of biofeedback. Squeeze duration was better in the biofeedback group (P = 0.019). On the outcome measure of no incontinence in a one week diary, 86% (six out of seven) of biofeedback patients and 45% (five of 11) of education without biofeedback participants were "complete responders" (Analysis 3.20).

Norton (Norton 2003) compared education and advice, with or without exercises, with or without biofeedback (clinic and home or clinic alone) in 171 patients. No significant differences between the groups were reported on manometric parameters, continence scores, quality of life, anxiety and depression, diary data and self-rating.This study consisted of four groups and consequently fits with comparison 3 and 6 below. No data were given in a format suitable for statistical analysis in RevMan.

Group 1: education (advice and information on bowel re-training).

Group 2: education and sphincter exercises.

Group 3: education, sphincter exercises and clinic biofeedback.

Group 4: education, sphincter exercises, clinic biofeedback and home biofeedback daily.

Education plus exercises versus education alone

In the groups comparing education plus sphincter exercises (43 patients) with education alone (37 patients) there were no reported difference between the groups for any of multiple outcomes on an intention-to-treat analysis immediately after and at one year follow-up.

Education, sphincter exercises and clinic biofeedback versus education alone

In the groups comparing education plus sphincter exercises versus sphincter exercises plus clinic biofeedback versus sphincter exercises plus clinic and home biofeedback there were no statistically significant differences reported between the groups in the outcomes of manometry, scores, quality of life, diary, visual analogue scale, or anxiety and depression at the end of treatment nor at one year follow-up.

Education, sphincter exercises, clinic biofeedback and home biofeedback daily versus education alone

In the groups comparing education plus sphincter exercises versus sphincter exercises plus clinic biofeedback versus sphincter exercises plus clinic and home biofeedback there were no statistically significant differences reported between the groups in the outcomes of manometry, scores, quality of life, diary, visual analogue scale, or anxiety and depression at the end of treatment nor at one year follow-up.

Exercises plus habit re-training versus habit re-training alone

Whitehead included 18 participants. The data were not suitable for analysis in RevMan. After four weeks of exercises the median number of incontinent episodes per week was 0.70 for the exercise group and 0.54 for the no-exercise group. Measures of variation were not reported and it was not possible to perform any statistical analyses on these data. All patients underwent habit training. Alternate patients were initially assigned to sphincter exercises or no exercises. The main focus of the trial was, however, biofeedback therapy. All patients who failed to respond to the exercise phase were treated subsequently with biofeedback. Most of the results presented in the paper referred to this non-randomised phase and consequently were not analysed. No further data were available from the authors (Whitehead 1985).

4. Anal sphincter exercises/PFMT with or without biofeedback and another treatment versus exercises with or without biofeedback

Four trials were included in this comparison (Fynes 1999; Hinninghofen 2003; Mahony 2004; Schwandner 2010).

Exercises plus biofeedback plus electrical stimulation versus exercises plus biofeedback

The combined result of Fynes and Schwandner showed a statistically significant result favouring the addition of electrical stimulation to biofeedback over biofeedback alone for numbers failing to achieve full continence (RR 0.60, 95% CI 0.46 to 0.78) (Analysis 4.1). Participants were on average 40% more likely to achieve full continence in the electrical stimulation group compared with control.

Schwandner (Schwandner 2010) compared 'Triple target training' where amplitude-modulated middle-frequency electrical stimulation was combined with electromyography (EMG) biofeedback versus EMG biofeedback carried out at home daily for 20 minutes for a duration of nine months. Schwandner also showed a statistically significant result for the incontinence score favouring the addition of electrical stimulation (Analysis 4.6).

Fynes (Fynes 1999) compared vaginal pelvic floor manometric pressure biofeedback and home exercises taught by a continence nurse versus anal EMG biofeedback and home exercises in combination with anal electrical stimulation taught by a physiotherapist. The number of people with no improvement in their faecal incontinence symptoms was significantly lower in the electrical stimulation group (RR 0.06, 95% CI 0.00 to 0.91) (Analysis 4.2). 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 could not be computed from the range since this would result in an over-estimation of the standard deviation.

Mahony (Mahony 2004) compared exercises plus biofeedback plus anal electrical stimulation versus exercises and biofeedback in 54 women with obstetric-related faecal incontinence. However, most results given were intra-group rather than inter-group comparisons. The authors stated that there were no differences between the groups in continence scores, resting or squeeze pressures or quality of life.

Hinninghofen (Hinninghofen 2003) compared sphincter training with electrostimulation versus sphincter training with biofeedback. The data could not be analysed in RevMan.

5. Anal sphincter exercises/PFMT and biofeedback versus anal sphincter exercises/PFMT alone

Three trials were included in this comparison (Bols 2011; Heymen 2009; Hinninghofen 2003).

Bols (Bols 2011) evaluated rectal balloon therapy in addition to PFMT versus PFMT alone and reported that adding rectal balloon therapy was equally effective as PFMT alone in modifying the continence score of 5 points or more, and that added rectal balloon therapy was better than exercises alone on quality of life, manometric and global perceived effect measurements. The data were not suitable for statistical analyses in RevMan.

Heyman (Heymen 2009) compared manometric biofeedback and pelvic floor exercises with exercises alone. The number of people who failed to achieve full continence was significantly lower in the biofeedback and PFMT group (RR 0.70, 95% CI 0.52 to 0.94, Analysis 5.1). The number of people satisfied with the treatment (Analysis 5.3) was not significantly different between intervention groups.

Hinninghofen (Hinninghofen 2003) compared sphincter training with biofeedback versus pelvic floor training without support. The data could not be analysed in RevMan, only a brief abstract in German was available.

6. One type of biofeedback versus another type of biofeedback

Three trials were included in this comparison (Heymen 2000; Norton 2003; Solomon 2003).

Heyman (Heymen 2000) compared four different types of biofeedback: clinic EMG; clinic EMG plus rectal distension; clinic EMG plus home biofeedback; or clinic EMG plus rectal distension and home biofeedback. This trial reported no differences between the groups allocated to the different interventions. The data could not be analysed in RevMan.

Solomon (Solomon 2003) compared anal sphincter exercises (taught verbally and on digital examination) alone versus sphincter exercises plus ultrasound or EMG biofeedback in 120 patients. The data could not be analysed in RevMan. Solomon reported that there were no differences between the three groups in manometric measurements, continence scores, incontinence symptoms or quality of life at the end of treatment. The data for continence scores and manometric parameters are presented in 'Other data' tables (Analysis 6.7; Analysis 6.13).

Norton (Norton 2003) compared education, sphincter exercises and clinic biofeedback versus education, sphincter exercises, clinic biofeedback and home biofeedback. The data could not be analysed in RevMan. Norton stated that the addition of home biofeedback did not result in any statistically significant difference in incontinence scores, manometric measurements, quality of life, diary, or anxiety and depression measurements both at the end of treatment and at one year follow-up.

7. One type of anal sphincter exercises/PFMT versus another type of anal sphincter exercises/ PFMT

Two trials were included in this comparison (Bartlett 2011; Markwell 2006).

Bartlett compared a standard clinical protocol (sustained submaximal anal and pelvic floor exercises versus an alternative group (rapid squeeze plus sustained submaximal exercises) with biofeedback in both arms of the study (Bartlett 2011) and reported no difference in objective manometric measurements, Cleveland Clinic (Wexner) Fecal Incontinence score or the Fecal Incontinence Quality of Life Scale survey tool.

Markwell (Markwell 2006) compared one type of exercise versus another type of exercise, however there were no useable data for this review. One group (Group A) were taught a specific pelvic floor muscle action, abdominal muscle action, toilet dynamics and dietary advice; the other group (Group B) were taught a standard pelvic floor muscle exercise and were provided with the same dietary advice. Markwell (Markwell 2006) reported that those in

Group A were significantly more happy with their symptoms than those in Group B, at three months.

One trial with a complex cross-over design with only eight patients did not report data in sufficient details to be analysed in RevMan (Latimer 1984).

DISCUSSION

Summary of main results

Some studies have suggested that there is no difference between different conservative interventions and that adding exercises or biofeedback, or both, does not enhance the outcomes of conservative management (Norton 2003). However, subsequent studies have used a step-wise protocol, trying the simpler interventions first and then only recruiting those who fail to respond to simpler measures such as diet and education (Bols 2011: Heymen 2009). These later studies have found a difference between exercise alone and exercise with the addition of rectal balloon (Bols 2011) or EMG biofeedback (Heymen 2009) in favour of adding biofeedback.

There was not enough evidence to say whether different methods of providing feedback made a difference (Heymen 2000; Norton 2003; Solomon 2003) because the trials were small.

Addition of electrical stimulation to biofeedback and exercises may also enhance results (RR 0.60, 95% CI 0.46 to 0.78) (Fynes 1999; Schwandner 2010). A single trial in this review suggests that anal biofeedback is superior to vaginal, and that electrical stimulation might enhance the results of exercises (Fynes 1999). However, the trial focused on the use of electrical stimulation as an adjunct to biofeedback and compared two very different types of interventions (vaginal pelvic floor manometric pressure biofeedback and home exercise with anal EMG biofeedback and home exercises in combination with anal electrical stimulation) and did not single out just the effects of electrical stimulation or biofeedback. Moreover, it is difficult to know how much of this improvement is a consequence of the natural history of faecal incontinence following childbirth as a no-treatment group was not included.

In one small trial (Tjandra 2008) showed that sacral nerve stimulation was better than conservative management which consisted of biofeedback and PFMT.

One small trial (Schwandner 2011) showed that adding biofeedback to electrical stimulation was better than electrical stimulation alone (RR for failing to achieve full continence 0.47, 95% CI 0.33 to 0.65).

One small trial (Heymen 2009) comparing manometric biofeedback and pelvic floor exercises with exercises alone showed a statistically significant result for number of people failing to achieve full continence favouring biofeedback (RR 0.70, 95% CI 0.52 to 0.94).

It appears also that training to enhance rectal discrimination of sensation may be helpful in reducing faecal incontinence (Bols 2011; Miner 1990). It may be that adding this technique to the more commonly available pelvic floor muscle training (PFMT) would enhance results, but this cannot be a strong recommendation in view of the small numbers and lack of follow-up data (Bols 2011).

Further conclusions are not warranted from the available data.

Overall completeness and applicability of evidence

There was a wide variation among trial reports in terms of characteristics of participants, characteristics of interventions, choice of outcome measures, duration of treatment and length of follow-up. Most of the trials were small and probably of insufficient power to detect any differences between intervention groups. The outcome measures used were often insufficiently reported to enable further statistical analyses. Length of follow-up was not clearly reported or was inadequate in many of the trials. The way in which data were reported in many of the trials (by not reporting measures of variance) made a quantitative synthesis of results (meta-analysis) impossible.

Quality of the evidence

Randomised controlled trials are thought to provide sound evidence on the effects of healthcare interventions mainly because they can eliminate selection bias. Methodological weaknesses in some studies included in this review are likely to have compromised this assumption. About half of the trials had low risk of bias for randomisation and allocation concealment.

Potential biases in the review process

It should be noted that pressure and EMG measurements may not be comparable between different studies because of equipment and technique variations. Within-study changes should be more reliable. There are no direct 'objective' measures of faecal incontinence. Changes in anorectal physiology measurements are proxy outcome measures and need not mean changes in the patient's symptoms, which should be seen as the primary end-point.

Agreements and disagreements with other studies or reviews

There are over 60 uncontrolled trial reports in the literature on the use of biofeedback for the management of faecal incontinence in adults (Norton 2009). Some authors maintain that biofeedback is the treatment of choice for faecal incontinence on the basis of the findings of these observational studies. The results of this review show that there is some evidence from randomised controlled trials to support the effectiveness of biofeedback therapy for the management of people with faecal incontinence. All studies reviewed showed improved symptoms in all groups, and some difference between groups are reported in the latest studies in favour of adding biofeedback or electrical stimulation.

AUTHORS' CONCLUSIONS

Implications for practice

We found no evidence that one method of biofeedback or exercises gives any benefit over any other method, but biofeedback or electrical stimulation may offer an advantage over exercises alone if patients have previously failed to respond to other conservative managements. Addition of biofeedback to surgical sphincter repair does not appear to improve the outcome (Davis 2004). On the whole, it is not possible to draw strong conclusions for practice from the data analysed in this review. In particular, there is not enough evidence on which to select patients suitable for anal sphincter exercises or biofeedback, or both; nor to know which modality

of biofeedback or exercises is optimal. Reducing the threshold of discrimination of rectal sensation does seem to be clinically useful (Miner 1990). Electrical stimulation or anal biofeedback, or both, may be superior to vaginal biofeedback in women with symptoms after childbirth (Fynes 1999). One trial (Tjandra 2008) included in this review found sacral nerve stimulation to be superior to exercises. However, based on the available evidence these conclusions can only be tentative. No study reported any adverse events or deterioration in symptoms, and it seems unlikely that these treatments may cause any harm.

Treatment options for faecal incontinence have not yet been investigated by means of well-designed trials. A Cochrane review of surgery for faecal incontinence (Brown 2010) failed to draw conclusions about the effectiveness of different surgical interventions mainly because of the dearth of controlled clinical trials concerning the most common operations (for example anterior overlapping anal sphincter repair). Another Cochrane review on drug treatments failed to draw firm conclusions on the efficacy of current pharmacological interventions (Cheetham 2002).

Implications for research

There is a need for well-designed randomised controlled trials with adequate sample sizes, validated outcome measures and long-term follow-up. In particular, studies should assess the effectiveness of different components of the package of care often called 'biofeedback', including exercises, feedback on sphincter function, rectal sensitivity training and co-ordination training, as well as lifestyle advice that is often given to patients during the course of consultation (e.g. dietary advice, use of medication, bowel habit information). Comparisons of intensive versus less intensive exercise regimens would be useful, as would measurement of compliance with exercises and advice. Little attention seems to have been given to the patient's perspective on outcome in the published studies, and there is no information on what patients view as a good or satisfactory outcome of treatment for faecal incontinence. Economic analyses should also be incorporated into future trials.

There is a need for trials comparing exercises or biofeedback, or both, to other treatments such as medication, dietary manipulation or surgery. In all future studies there is a need to characterise the participants in detail so that judgements can be made on which treatments are of benefit to which diagnostic categories.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

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

Bartlett 2011

Methods	Randomised clinical study. Analysis not intention to treat.
Participants	Setting and country: single hospital anorectal physiology clinic, Australia. Inclusion criteria: faecal incontinence had failed to respond to conservative treatment prescribed by general practitioners over a 6 to 12 month period. Exclusion criteria: none stated Number of participants:101 approached (26 had moved, 2 excluded, one refused) 72 recruited; 69 completed treatment; 53 completed follow-up Age: mean age 62.1 years (range 32-82) Sex: 53 women, 19 men Other characteristics of participants:
Interventions	Standard clinical protocol (37 participants: sustained submaximal anal and pelvic floor exercises. Alternative group (35 participants: rapid squeeze plus sustained submaximal exercises) with biofeedback in both arms of the study 5 outpatient sessions over 8 weeks. First 4 sessions were weekly; participants then practised techniques for 4 weeks before returning for their final session.
Outcomes	Cleveland Clinic (Wexner) Fecal Incontinence score Fecal Incontinence Quality of Life Scale survey tool Anorectal function - manometric measurements Follow-up period: 2 years (n = 53)
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	'Independent unrestricted randomization was performed before study commencement using a computer-generated sequence'
Allocation concealment (selection bias)	Unclear risk	Study arm placed in a sealed opaque envelope with the participant identification number on the front and given to the therapist immediately before session 3
Blinding (performance bias and detection bias)	Unclear risk	Participants were blinded. Researcher received the randomisation sequence immediately before analysis

Bartlett 2011 *(Continued)*

All outcomes		
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	69/72 completed. 53/72 available at 2 years. Patients who did not complete the programme were treated as missing. Quality of life assessment - 35 out of 37 available for sustained exercise group and 34 out of 35 available in rapid and sustained exercise

Bols 2011

Methods	Randomised controlled trial. Analysis intention to treat: missing values used multiple imputation procedure.
Participants	Setting and country: Single University Hospital Medical Centre, Netherlands. Inclusion criteria: Adults with faecal incontinence. Vaizey score of at least 12, faecal incontinence lasting at least six months, failure of dietary measures and medication. Exclusion criteria: not stated. Number: 80 participants Age: mean 59.3 (sd ± 11.9) Sex: not stated Other characteristics of participants: groups comparable on demographics at baseline.
Interventions	40 patients rectal balloon therapy re-training sensory threshold and coordination, with PFMT. 40 patients PFMT (strength, duration, timing and co-ordination of contraction) alone. 12 sessions with a physiotherapist using a standardised protocol, within nine weeks.
Outcomes	Patients evaluated at mean of 6.8 weeks (SD = 5.3). Primary outcome (subjective) based on Vaizey score ranging from 0 (complete continence) to 24 (complete incontinence) Fecal Incontinence Quality of Life (FIQL) Nine point global perceived effect (GPE) score PERFECT pelvic floor assessment Objective measures were anorectal manometry, rectal capacity measurement, anorectal sensation, anal endosonography and defecography Follow-up period: mean 6. 8 weeks (SD 5.3) after end of treatment
Notes	Recruited from August 2006 to May 2009. Abstracts and protocol only available at time of this review.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Block randomised by means of a computer generated list

Bols 2011 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	Researchers were blinded to treatment assignment
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Researchers were blinded to treatment assignment
Incomplete outcome data (attrition bias) All outcomes	Low risk	Ten patients (12.5%) dropped out during or after treatment. Completion rates did not differ between groups (P = 0.31)

Davis 2004

Methods	Randomised controlled trial. Analysis not intention to treat.
Participants	Setting and country: single hospital centre UK. Inclusion criteria: 43 female patients underwent sphincter repair for obstetric external sphincter defect: 38 consented to randomisation: 31 available for follow up. Exclusion criteria: congenital abnormalities, IBS, rectal prolapse, rectocoele, non-obstetric trauma "anorectal conditions" (number not stated). Number of participants: 38 randomised; 31 completed Age: mean 60.48 years (SD 11.92). Sex: all 38 were women. Other characteristics of participants: 30/31 completing were parous. Groups comparable for age, parity and duration of symptoms.
Interventions	All patients had an anal sphincter repair. Intervention: anal sphincter repair plus biofeedback which commenced three months after surgery (written and verbal information, one therapist, sessions 1 hour per week for 6 weeks, individualised exercise programme, home exercises: biofeedback: 2 balloon manometry for amplitude and duration of squeeze, isolate from abdominal effort: auditory or visual feedback; sensory training Control: anal sphincter repair only.
Outcomes	Visual analogue scale for subjective outcome; quality of life; continence score; manometry Follow-up period: 12 months after surgery (9 months after start of biofeedback).
Notes	Most data presented as before-after analysis rather than between group analysis.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer generated list of random numbers
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Davis 2004 *(Continued)*

Blinding (performance bias and detection bias) All outcomes	Unclear risk	Blinding not mentioned
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	38 randomised: 7 withdrew or lost to follow-up

Fynes 1999

Methods	Randomised controlled trial. Analysis: not intention to treat.
Participants	Setting and country: single centre, Dublin, Ireland. Inclusion criteria: consecutive women with faecal incontinence caused by obstetric trauma presenting to a dedicated perineal clinic. Exclusion criteria: none stated. Number of participants: 40, one withdrawal Age: mean 32 years (range 18-48 years) Sex: 40 women Other characteristics of participants: mean duration of symptoms 4 months (range 3-28 months). 37 women were symptomatic after primary repair of recognised anal sphincter disruption, and 3 after traumatic instrumental delivery with no attempt at repair. 24 were primiparous, and 16 were multiparous. No significant differences between the two groups in age, parity or duration of symptoms.
Interventions	Group 1: Sensory biofeedback: by continence nurse using Peritron perineometer vaginal probe. Weekly 30-minute sessions for 12 weeks. Fast twitch: aim for 20 short maximum contractions of 6-8 seconds, 10 seconds relaxation between. Slow twitch: aim for 30 seconds duration. Patients treated supine. Group 2: Augmented biofeedback: weekly sessions with a specialist physiotherapist using Incare PRS 9300 computer with anal probe to give audiovisual EMG feedback and electrical stimulation. Patient in left lateral position. 13-second cycles: 5 seconds activity, 8 seconds rest, for 15 minutes. Slow twitch: hold for 5 seconds, fast twitch: 3 fast contraction in 5 seconds, alternating. Then electrical stimulation, 20% ramp: 20Hz for 10 minutes (5 seconds stimulation, 8 seconds rest); then 50Hz, time unspecified, 8 seconds stimulation with 30 seconds rest. Both groups advised to practice "standard Kegel pelvic floor exercises" at home (instructions not reported).
Outcomes	Anorectal manometric parameters (resting, squeeze and squeeze increment pressures and a vector symmetry index), symptom questionnaire and continence scores Follow-up period: 12 weeks treatment only.
Notes	Compared two completely different treatments, with different therapists. The authors claim that the difference in outcome is attributable to electrical stimulation is questionable.

Risk of bias

Bias	Authors' judgement	Support for judgement

Fynes 1999 *(Continued)*

Random sequence generation (selection bias)	Low risk	Computer generated using Ran List
Allocation concealment (selection bias)	Unclear risk	Not mentioned
Blinding (performance bias and detection bias) All outcomes	Low risk	Therapist blind to obstetric history and previous test findings. Outcome assessor blind to treatment group.
Incomplete outcome data (attrition bias) All outcomes	Low risk	40 randomised, one dropout

Healy 2006

Methods	Randomised trial. Analysis: not intention to treat.
Participants	Setting and country:single hospital centre in Ireland. Inclusion criteria: not stated. Exclusion criteria: significant anal sphincter disruption. Number of participants: 58 randomised; 48 completed Age: mean age 55 years (range 40-78) Sex: 58 women Other characteristics of participants:
Interventions	Previously excluded stool softening foods for 1 month. 1. Endo-anal pudendal nerve stimulation daily at home using Anuform anal probe for 1 hour. 2. Attended physiotherapy department for endo-anal electrical stimulation under supervision. Alternating EMG biofeedback and electrical stimulation using augmented biofeedback. Stimulation alternating 15 minute cycles at 10Hz and 40Hz. 3 months intervention.
Outcomes	Manometry PNTML Cleveland Clinic (Wexner) faecal incontinence score Generic quality of life (SF-36) Follow-up period: end of treatment.
Notes	Trial lasted 3 years

Risk of bias

Bias	Authors' judgement	Support for judgement

Healy 2006 *(Continued)*

Random sequence generation (selection bias)	Unclear risk	Not mentioned
Allocation concealment (selection bias)	Unclear risk	Not mentioned
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Not mentioned
Incomplete outcome data (attrition bias) All outcomes	High risk	10 of 58 dropped out with no reporting of outcomes

Heymen 2000

Methods	Randomised controlled trial. Analysis: not intention to treat.
Participants	Setting and country: single centre USA. Inclusion criteria: non-surgical candidates based on clinical, manometric and electrophysiological parameters. Exclusion criteria: eligible for surgical management. Number of participants: 40 randomised: 6 withdrew after one session: 34 analysed Age: mean 74 years (range 36-88) Sex: 23 female, 11 male Other characteristics of participants: mean Wexner score 12 (range 7-14).
Interventions	Group 1: Feedback display of EMG activity of intra-anal EMG plus education as to pelvic floor physiology and operant conditioning techniques to retrain function. Group 2: Outpatient EMG biofeedback plus balloon distension sensory training. Group 3: Outpatient BF plus HT EMG biofeedback for home practice. Group 4: Outpatient biofeedback training plus in session balloon distension sensory training plus HT unit for practising exercises.
Outcomes	Diary: Days per week with incontinence episodes Follow-up period: immediately after treatment only.
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer generated randomisation method
Allocation concealment (selection bias)	Unclear risk	Not mentioned

Heymen 2000 *(Continued)*

Blinding (performance bias and detection bias) All outcomes	Unclear risk	Not mentioned
Incomplete outcome data (attrition bias) All outcomes	High risk	40 randomised: 6 withdrew: 34 analysed

Heymen 2009

Methods	Randomised controlled trial. Analysis: intention to treat.
Participants	Setting and country: single centre. Tertiary referral hospital in USA. Inclusion criteria: consecutive series of "chronically incontinent patients referred to University of North Carolina Hospitals". At least 1 teaspoon of faeces at least weekly; anatomic defects on anal ultrasound permissible. Exclusion criteria: flatus incontinence and staining only; psychotic disorder and severe cognitive impairment Number of participants: 168 randomised. After run-in period of conservative management, 108 started intervention as randomised. Age: average 59.6 years Sex: 83 female, 25 male Other characteristics of participants:
Interventions	PFMT alone 63 participants. PFMT plus manometric biofeedback 45 participants. Both groups taught behavioural strategies to avoid incontinence.
Outcomes	Primary: Faecal Incontinence Severity Index (FISI) Secondary: Days per week incontinent; complete continence (no staining); squeeze pressure and abdominal tension; Faecal incontinence quality of life score (FI-QoL); telephone report to therapist of "adequate relief"
Notes	Randomised patients prior to run-in period which resulted in unbalanced group sizes: 35 patients reported adequate relief from run-in and 24 withdrew, resulting in 109 patients only entering treatment phase.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Co-investigator produced the randomisation table using random number generator
Allocation concealment (selection bias)	Unclear risk	Group membership was reported to the therapist after patient arrived for initial visit. Patients randomised prior to unblinded run-in phase

Heymen 2009 *(Continued)*

Blinding (performance bias and detection bias) All outcomes	High risk	Therapist telephoned participant to ask if they had experienced "adequate relief"
Incomplete outcome data (attrition bias) All outcomes	Low risk	Intention-to-treat analysis reported: authors replaced missing values with zero

Hinninghofen 2003

Methods	Randomised controlled trial. Analysis: unclear if intention to treat.
Participants	Setting and country: Germany Inclusion criteria: patients of incontinence clinic Exclusion criteria: none stated Number of participants: 65 randomised Age: 65 ± 12.4 Sex: not stated Other characteristics of participants: none stated
Interventions	1.Sphincter training with biofeedback machine (26 participants) 2. Sphincter training with electrostimulation (18 participants) 3. Pelvic floor training without support (21 participants) 3 months intervention
Outcomes	Rockwood faecal incontinence quality of life score; general quality of life score Dupey et al 1994; Wexner incontinence score.
Notes	Brief abstract in German only.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No information
Allocation concealment (selection bias)	Unclear risk	No information
Blinding (performance bias and detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information

Ilnyckyj 2005

Methods	Randomised controlled trial. Analysis: not intention to treat.
Participants	Setting and country: single centre, Canada. Inclusion criteria: women with regular and frequent "idiopathic" FI; bowel imaging within past 2 years. Exclusion criteria: diabetes with neuropathy, neurological disease, less than 6 months since childbirth, IBS, sphincter injury amenable to surgery. Number of participants: 23 of 54 screened met study criteria. Withdrawals: 5, groups not specified Age: mean 59 years (range 26-75) Sex: 23 women, 0 men Other characteristics of participants: mean parity 3
Interventions	Group 1 education and anal sphincter exercises. Group 2 education and manometric BF therapy.
Outcomes	Success defined as no incontinence episode during last week of study Manometry Follow-up: end of study.
Notes	Probably under powered to detect a difference.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No mention
Allocation concealment (selection bias)	Unclear risk	No mention
Blinding (performance bias and detection bias) All outcomes	Unclear risk	No mention
Incomplete outcome data (attrition bias) All outcomes	High risk	23 randomised 5 drop outs. Of 18 completers, 7 in biofeedback, 11 in education group

Latimer 1984

Methods	Single case experiments to examine three components of biofeedback. Cross-over design. Analysis: intention to treat. Allocation: patients randomly assigned to treatment B or C after A (see interventions). Design ABACADA or ACABADA.

Latimer 1984 *(Continued)*

Participants	Setting and country: single centre, Canada. Inclusion criteria: recruited from colleagues. Exclusion criteria: none stated. Number of participants: 8 subjects (4 adults and 4 children) Age: mean age: 49 years for adults and 11 years for children (range 8-72) Sex: 4 males, 4 females Other characteristics of participants: heterogeneous pathologies.
Interventions	4 phases to study: A - one month self-monitoring diary. B - sphincter strengthening exercise training (squeeze anus in response to rectal balloon inflation: 50 trials over 2 hours, verbal feedback only). C - rectal sensory discrimination training (2-3 second balloon inflations, decreased in 5-10ml steps, verbal reinforcement, 50 trials over 2 hours). D - biofeedback (B+C + biofeedback using 3-balloon system to demonstrate recto-anal inhibitory reflex and teach appropriate external anal sphincter contraction in response to reflex internal anal sphincter relaxation, visual feedback of performance. Two hour session weekly for 4 weeks using manometric anal probe. Same number of learning trials and same time with therapist at each session. Weekly contact by phone. Also allowed to use laxatives or enemas.
Outcomes	Daily diary of accidents, stains and changes of underwear throughout, returned weekly by post when not attending. Manometry before, after and at 6 months follow-up Follow-up period: each phase 4 weeks duration (28 weeks total).
Notes	Participants randomised to order of components only; insufficient data at the end of each phase to enable analysis.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No mention
Allocation concealment (selection bias)	Unclear risk	Patients randomly assigned to treatment B or C after A (see interventions). Design ABACADA or ACABADA
Blinding (performance bias and detection bias) All outcomes	Unclear risk	No mention of blinding
Incomplete outcome data (attrition bias) All outcomes	Low risk	No withdrawals

Mahony 2004

Methods	Randomised controlled trial. Analysis: not intention to treat.

Mahony 2004 *(Continued)*

Participants	Setting and country: single centre, Ireland. Inclusion criteria: consecutive women with FI after obstetric injury attending a perineal clinic. Exclusion criteria: Diabetes, IBS, IBD, previous ano rectal surgery, malignancy. Number of participants: 60 Age: range 22 to 42 Sex: 60 women Other characteristics of participants: median parity one
Interventions	Group 1: Intra-anal EMG BF weekly for 12 weeks. Group 2: Intra-anal EMG BF plus 20 mins with 5 second stimulation and 8 seconds relaxation between contractions. Intra-anal EMG BF plus electrostimulation at 35 Hz with a 20% ramp modulation time. Stimulation.
Outcomes	Questionnaire and faecal incontinence quality of life scale, continence score and manometry Follow-up period: end of treatment.
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated allocation
Allocation concealment (selection bias)	Low risk	Opaque envelopes
Blinding (performance bias and detection bias) All outcomes	Unclear risk	No mention
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	60 randomised 6 withdrawals: 4 from biofeedback, 2 from electrostimulation

Markwell 2006

Methods	Randomised trial. Analysis not intention to treat. First stage (3 months) parallel group design then participants were asked if they wanted to cross-over to the treatment arm.
Participants	Setting and country: single centre, Australia. Inclusion criteria: self reported inability to perceive loss on more than one occasion.

Markwell 2006 *(Continued)*

	Exclusion criteria: dementia unable to understand written and spoken English, lack of abdominal muscle innervation, previous pelvic floor treatment. Number of participants: 111 Age: mean 62 years (SD 12) Sex: 87 women, 24 men Other characteristics of participants: mean length of incontinence 7.85 years.
Interventions	A. dietary modification, stool bulking agents, specific pelvic floor muscle action using abdominal muscles, defecation training, 54 participants. B. dietary modification, stool bulking agents, conventional pelvic floor exercise, 57 participants.
Outcomes	visual analogue scale for happiness with symptoms and happiness with physiotherapy programme, bowel diary, rectal sensation, descending perineum syndrome Follow-up period: immediate (70/111) and one year (63%).
Notes	Unpublished study only reported in lengthy and unclear report.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated, stratified by gender and structural sphincter damage
Allocation concealment (selection bias)	Low risk	Opaque envelopes
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Single blind mentioned but who was blinded is unclear
Incomplete outcome data (attrition bias) All outcomes	High risk	45 completed in Group A out of 54 49 completed in Group B out of 57 36 in Group A went on to Group B protocol after Stage 1

McHugh 1986

Methods	Randomised controlled trial. Analysis: unclear if intention to treat. Allocation: randomised to biofeedback or exercises, cross-over design.
Participants	Setting and country: single centre, Canada. Inclusion criteria: regular and frequent (more than 8 of 28 days) "idiopathic" FI. Exclusion criteria: 93 patients who responded to initial dietary manipulation excluded. Number of participants: 18. 5 of 18 dropped out (all from exercise group) Age: mean 55.2 ± 11.4 years

McHugh 1986 *(Continued)*

Interventions	Biofeedback - standardised protocol - 3 sessions over 2 months. No details given. Exercises: Daily voluntary sphincter exercise programme using a home manometer.
Outcomes	Daily diaries of stains, accidents and stools Follow-up period: 8 months study duration.
Notes	Abstract only. Insufficient data to allow statistical analyses.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No mention
Allocation concealment (selection bias)	Unclear risk	B - Unclear
Blinding (performance bias and detection bias) All outcomes	Unclear risk	No mention of blinding
Incomplete outcome data (attrition bias) All outcomes	High risk	5 of 18 dropped out (all from exercise group)

Miner 1990

Methods	Two phase randomised controlled trial. Analysis: unclear if intention to treat.
Participants	Setting and country: single centre, UK. Inclusion criteria: incontinence on one month diary. Exclusion criteria: not incontinent on one month diary Number of participants: 28 consecutive patients, 3 excluded as not incontinent on one month diary, 25 entered study Age: 17-76 years Sex: 8 men 17 women Other characteristics of participants: heterogeneous diagnoses. 5 had previous post-anal repair, 2 inflammatory bowel disease; many also irritable bowel symptoms. Mean parity of women 4.2.
Interventions	One month diary, then phase 1 for 4 weeks (controls 8 weeks); then random allocation in phase 2 : strength or co-ordination training, all crossed-over. Allocation: random allocation to sensory training or sham. Phase 1: Rectal discrimination versus sham training: random allocation to 3 x 20 minute sessions (within 3 days) of rectal discrimination training - taught to recognise small volumes in rectal balloon and abolish any sensory delay (controls sham training with no feedback), controls cross-over to active after 1 month).

Miner 1990 *(Continued)*

	Phase 2: All then randomised to strength or co-ordination training, crossed over after 1 month. Strength training: 3 20-minute sessions within 3 days, encouraged to hold a maximal contraction for at least 20 seconds, then 4 exercise periods per day of 4 x 20second squeezes, resting for 20 seconds between, for 1 month. Co-ordination training: 3 sessions within 3 days: aim for maximal voluntary contraction within 0.5 seconds of balloon inflation and not allow pressure to fall below pre-inflation level (oppose recto-anal inhibitory reflex).
Outcomes	Diary - frequency of defecation, urgency and incontinence, manometry (resting and squeeze pressures and sensory threshold of rectal balloon distension) and questionnaire Follow-up period: outcomes at end of each treatment phase and at 12 month follow-up.
Notes	Sufficient data for analysis only from Phase 1.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No mention
Allocation concealment (selection bias)	Unclear risk	No mention
Blinding (performance bias and detection bias) All outcomes	Unclear risk	No mention of blinding
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No withdrawals

Naimy 2007

Methods	Randomised trial. Analysis not intention to treat.
Participants	Setting and country: single centre, Norway Inclusion criteria: women after 3rd or 4th degree perineal rupture during childbirth. Any grade of anal incontinence Exclusion criteria: major anal sphincter defect requiring surgical repair (only those with major symptoms were scanned by anal ultrasound); primary or secondary anal sphincter repair less than 12 months ago; pregnancy; inflammatory bowel disease or diarrhoea for other reasons. Number of participants: 49 Age: mean age 36 years (range 22-44) Sex: 49 women Other characteristics of participants: mean parity 2.1 (range 1-4).
Interventions	1. Biofeedback: Neuro Trac ETS:using Anuform anal probe. Quick 3 second squeeze; 10 second squeeze; squeeze for as long as it kept 50% of 3 second amplitude. Each squeeze repeated 5 times with equal rest time between. Initial session 30 minutes with 30 minute follow-up session 1 week later. Then daily 30 minute session at home for 8 weeks.

Naimy 2007 *(Continued)*

	2. Electrical stimulation: Neuro Trac ETS: 30 or 40Hz at alternate sessions; pulse width 200 µsec; upper limit 80 mAmp using Anuform anal probe. Patient turned up to maximum voltage which caused no discomfort. 3 seconds on 3 seconds rest for 20 minutes twice daily at home. Initial session 30 minutes with 30 minute follow-up session 1 week later. Both 2 times daily for 8 weeks.
Outcomes	Cleveland Clinic (Wexner) FI score (primary outcome); Faecal incontinence quality of life score (FIQLS); visual analogue for quality of life; patient self-rating of treatment effect (visual analogue score). Compliance monitor incorporated into equipment Follow-up period: end of treatment.
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computerised randomisation list
Allocation concealment (selection bias)	Unclear risk	No mention
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	40/49 completed: 19 in biofeedback and 21 in electrical stimulation

Norton 2003

Methods	Randomised controlled trial. Analysis: intention to treat.
Participants	Setting and country: Single centre, UK Inclusion criteria: 18+ years, referred for symptoms of incontinence regardless of frequency or severity. Exclusion criteria: major structural sphincter disruption; previous BFB or exercises, neurologic disease, cognitive impairment, IBD, need urgent medical referral, insufficient written English. Number of participants: 171 randomised, 140 completed Age: Mean age 56 (range 26 to 85) Sex:12 men, 159 women Other characteristics of participants: 93% of women parous, median 2 vaginal deliveries.
Interventions	Median of 5 sessions with the same therapist. Group 1: up to 6 one hour sessions of advice and information plus bowel re-training. Group 2: as group 1plus 50 anal sphincter contractions per day (taught on digital examination). Group 3: as group1 plus computer BFB to teach anal sphincter exercises.

Norton 2003 *(Continued)*

	Group 4: As group 3 plus 20 mins home EMG BFB daily.
Outcomes	Patient rating, manometry, questionnaire, diary, score, SF36, HADS Follow-up period: 1 year after finishing treatment.
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated numbers
Allocation concealment (selection bias)	Low risk	Opaque brown envelopes
Blinding (performance bias and detection bias) All outcomes	Low risk	Outcome assessor for repeat manometry
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	171 randomised, 140 completed. No difference between groups in completion rates

Schwandner 2010

Methods	Randomised controlled trial. Analysis intention to treat.
Participants	Setting and country: multicentre (8 sites) in Germany. Inclusion criteria: patients with anal incontinence deemed capable of independent training; over 18 years. Exclusion criteria: retention/overflow incontinence; complete rectal prolapse; chronic inflammatory bowel disease; definite or possible pregnancy. Number of participants: 158: 7 withdrew consent before commencing therapy Age: mean 64 in group 1, 62 in group 2 Sex: 138 female, 13 male Other characteristics of participants:
Interventions	1. "Triple target training": amplitude-modulated middle-frequency stimulation with current amplitude high enough to achieve perineal contraction; EMG-triggered and EMG-controlled exercises. 2. Biofeedback: training at home for 20 minutes twice daily while standing. 3-8 second squeeze with pause of 10-15 seconds. Need to activate puborectalis. Both interventions daily for 20 minutes at home for 9 months.
Outcomes	Primary: Cleveland Clinic incontinence score at 9 months (Wexner score); Vaizey score at 9 months

Schwandner 2010 *(Continued)*

	Secondary: change from baseline in Cleveland Clinic incontinence score (Wexner score) and Vaizey score at 3 and 6 months; Faecal Incontinence Quality of life Score; acceptance and compliance; changes from baseline in stool-modifying drug use. Follow-up period: 9 months.
Notes	Note large and differential dropout rate (see below).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Generated by a clinical trials centre: self-adjusting design of Nordle and Brandtmark was used with centre and incontinence grade as column variables and gender as row variable
Allocation concealment (selection bias)	Low risk	Telephone communication after registration form available
Blinding (performance bias and detection bias) All outcomes	Low risk	Open label with blinded observers for secondary outcome measures. Person handing out patient self-completion questionnaire was blinded to allocated group
Incomplete outcome data (attrition bias) All outcomes	High risk	Report an intention-to-treat analysis: patients who dropped out assumed to have no change. However, there was a large and differential dropout rate between the groups which jeopardises the randomisation and the validity of the intention-to-treat analysis. Biofeedback: 19 of 79 completed; Triple therapy: 43/79 completed

Schwandner 2011

Methods	Multicentre randomised trial, open parallel group design.
Participants	Anal incontinence of Grade 1 or higher, 18% had endosonographically diagnosed sphincter damage
Interventions	80 participants. 1. "Triple target training": amplitude-modulated middle-frequency electrical stimulation with current amplitude high enough to achieve perineal contraction plus electromyographic (EMG) biofeedback and EMG-controlled exercises 39 participants. 2. Standard treatment low frequency electrical stimulation 41 participants.
Outcomes	Cleveland clinic score, proportion of patients regaining continence, quality of life
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation performed centrally by telephone
Allocation concealment (selection bias)	Low risk	Randomisation performed centrally by telephone

Schwandner 2011 *(Continued)*

Blinding (performance bias and detection bias) All outcomes	Low risk	Blinded observer

Solomon 2003

Methods	Randomised controlled trial. Analysis: not intention to treat.
Participants	Setting and country: single centre, Australia. Inclusion criteria: failed dietary and medical treatment. Exclusion criteria: No anatomic defect in external sphincter, IBD, peri-anal inflammation, diarrhoea, rectal prolapse. Number of participants: 120 randomised, 102 completed Age: mean age 62 years Sex:107 women, 13 men Other characteristics of participants:
Interventions	Five thirty minute sessions over four months. Group 1: Anal sphincter exercises taught on digital examination. Group 2: Anal sphincter exercises taught with transanal ultrasound feedback. Group 3: Anal sphincter exercises taught with manometric feedback.
Outcomes	Scores, VAS, investigators assessment, quality of life, manometry, fatigue rate Follow-up period: end of treatment.
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Opaque envelopes organised centrally
Allocation concealment (selection bias)	Low risk	Opaque envelopes organised centrally
Blinding (performance bias and detection bias) All outcomes	Low risk	Outcome assessor blinded
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	120 randomised, 102 completed (groups not stated)

Tjandra 2008

Methods	Randomised study over 12 months. Analysis not intention to treat.
Participants	Setting and country: Single centre in Australia. Inclusion criteria: severe faecal incontinence. Exclusion criteria: rectal prolapse; inflammatory bowel disease; congenital ano-rectal malformation; neurological disorders; stoma in situ; pregnancy; external anal sphincter defect of more that 120 degrees; bleeding diathesis; mental or physical disability precluding adherence to study protocol. Number of participants: 120 Age: 39-86 years Sex: Mostly women, figures not given Other characteristics of participants: most had previous sphincter repair.
Interventions	1. Optimum medical therapy, including pelvic floor exercises, bulking agents, dietary management of fluid and fibres with team of physiotherapists and dietitians. Attended varied with need, usually monthly for 6 months then 2 monthly. 2. two phase sacral nerve stimulation: peripheral nerve evaluation for at least 7 days. Patients with a 50% reduction or more in incontinence episodes were implanted with a permanent sacral nerve stimulator.
Outcomes	No primary outcome specified. Wexner incontinence score; Faecal Incontinence Quality of Life score; SF-12; bowel diary; manometric resting and squeeze pressure Follow- up period: 12 months.
Notes	Main focus of the paper was sacral nerve stimulation: exercise group was the control.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not mentioned
Allocation concealment (selection bias)	Low risk	Performed from central registry using sealed envelopes
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Not mentioned
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	7 patients in the SNS group did not proceed beyond the peripheral nerve evaluation stage

Whitehead 1985

Methods	Allocation: Alternate patients allocated to exercises or control, all underwent simultaneous habit training.

Whitehead 1985 *(Continued)*

	Analysis: unclear if intention to treat.
Participants	Setting and country: single centre, USA. Inclusion criteria: recruited by physicians or newspaper advertisement. Exclusion criteria: none stated. Number of participants: 18 Age: 65-92 (mean 73.3 years) Sex: 3 men, 15 women Other characteristics of participants: 6 doubly incontinent. 2 demented and 3 depressed.
Interventions	Initial habit training (attempted defecation after breakfast and use of enema if no bowel action for two days), bulk agents for 11 patients; alternate patients also instructed to perform 50 sphincter exercises per day for 10 seconds each, with no such instruction in controls. If still incontinent after 4 weeks of habit training plus exercises or control, all received biofeedback.
Outcomes	Incontinent episodes per week; manometric sphincter strength, rectal sensation. Follow-up period: 4 weeks.
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Allocation by alternate patients
Allocation concealment (selection bias)	High risk	Alternate patients allocated to exercises or control, all underwent simultaneous habit training. If still incontinent after 4 weeks of habit training plus exercises or control, all received biofeedback
Blinding (performance bias and detection bias) All outcomes	Unclear risk	No mention of blinding
Incomplete outcome data (attrition bias) All outcomes	Low risk	No dropouts

BFB: Biofeedback
EMG: Electromyography
FI: Faecal incontinence
HADS: Hospital Anxiety and Depression Scale
HT: Home trainer
IBD: Inflammatory bowel disease
IBS: Irritable bowel syndrome
SF36: Short Form-36
VAS: Visual analogue scale

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

Study	Reason for exclusion
Bates-Jensen 2003	Study of effect of general exercise on skin health
Byrne 2002	Quality of life study, not RCT
Chase 2004	Urinary incontinence only
Christensen 2009	intervention trans-anal irrigation not biofeedback
Cox 1996	Participants were children
Cox 2003	Participants were children
Croffie 2005	Participants were children
Dannecker 2004	Pre-natal exercises, participants did not have faecal incontinence
Enck 1994	Non-randomised trial
Fang 2003	Physiotherapy after stroke
Gaier 2010	Prevention study, women were randomised to supervised PFMT or usual care. Women were not fecally incontinent at start of study
Glazener 2005	Effect of post-natal exercises on urinary incontinence. Most participants did not have faecal incontinence at baseline
Gouldthorpe	Abdominal muscle training during pregnancy
Harari 2004	Effect of nursing advice on bowel function after stroke. Most participants did not have faecal incontinence at baseline
Heymen 2003	Only one group of patients
Heymen 2004	Pre-treatment prior to randomisation
Heymen 2004a	Pre-treatment prior to randomisation
Heymen 2005	Constipation not faecal incontinence
Jorge 1994	Intervention used for patients undergoing an ileo-anal pouch operation as a preventive measure, not as a treatment for current faecal incontinence.
Klijn 2003	Urinary incontinence
Leroi 2005	Surgical study of sacral nerve stimulation
Levy-Storms 2007	Participants included on basis of urinary incontinence. No data on faecal incontinence
Loening-Baucke 1988	Non-randomised trial in which participants were children
Loening-Baucke 1990a	Non-randomised trial
Loening-Baucke 1990b	Participants were children
Loening-Baucke 1995	Non-randomised trial in which participants were children

Study	Reason for exclusion
Markland 2009	Epidemiology study. No intervention
Mathew 2004	Wrote to authors to clarify contents and methodology. No reply received
Norton 2006	Electrical stimulation with no exercises or biofeedback
O'Brien 2005	Surgery (artificial bowel sphincter)
Oresland 1988	Intervention used for patients undergoing an ileo-anal pouch operation as a preventive measure, not as a treatment for current faecal incontinence
Osterberg 2004	RCT comparing surgery with electrical stimulation. No exercises or biofeedback
Pager 2002	Not an RCT
Pourmomeny 2011	Study covers constipation
Powell 2003	Abstract with no data
Richter 2011	Cohort study, inclusion all women who underwent a sphincter repair at time of singleton delivery. Investigation of faecal incontinence
Ritterband 2003	Participants were children
Roth 1999	Electrical stimulation only
Schnelle 2002	Effect of general mobility exercises in nursing home
Schnelle 2003	Effect of general mobility exercises in nursing home
Simmons 2005	Mobility and toileting intervention
Solomon 2000	Not an RCT
Surh 1998	Translation obtained, no mention of how patients were allocated. Written to authors
Tekeoglu 1998	TENS intervention for activities of daily living in stroke patients, no faecal incontinence
van der Plas 1996a	Participants were children
van der Plas 1996b	Participants were children
Wald 1984	Non-randomised trial. Rectal sensation of diabetic patients compared to non-incontinent diabetics and non-diabetic incontinent people. All incontinent diabetics received biofeedback
Wald 1987	Participants were children
Whitehead 1986	Participants were children

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

Marshall 1995

Methods	Not clear how participants were allocated to treatment
Participants	44 women with fecal incontinence after first delivery
Interventions	Transcutaneous electrical stimulation versus pelvic floor exercises
Outcomes	ICS draft questionnaire, visual analogue scales, resting and squeeze pressure, diary
Notes	

Pages 2003

Methods	Participants alternately assigned (used Google translate) this needs to be confirmed
Participants	Patients with fecal incontinence
Interventions	Biofeedback daily for 4 weeks Biofeedback daily for 4 weeks followed by a 2 month home exercise programme Electrostimulation for 3 months
Outcomes	Faecal frequency, subjective improvement, incontinence score
Notes	German paper, only English abstract, alternately assigned? need formal translation

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

Dehli 2009

Trial name or title	A randomized, controlled, clinical trial of biofeedback and anal injections as first treatment of fecal incontinence. ControlledTrials.com (www.controlled-trials.com) [accessed 2 February 2009] 2009.
Methods	Randomised study, blinded outcome assessor
Participants	Faecal incontinence lasting more than 6 months St Marks score of 4 or more No known local or general neurological disease 18 years or older No constipation
Interventions	Biofeedback versus anal injections
Outcomes	St Mark's incontinence score, quality of life, physiological parameters
Starting date	April 2006
Contact information	Trond Dehli, Department of gastroenterological surgery, University hospital North Norway, Breivika, 9038 Tromsø trond.dehli@unn.no tlf: +47 776 26 000

Dehli 2009 *(Continued)*

Notes	

Stott 2000

Trial name or title	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.
Methods	Randomised controlled trial
Participants	Patients with faecal incontinence
Interventions	PFMT plus biofeedback versus PFMT plus biofeedback plus electrical stimulation
Outcomes	Continence score, quality of life, anal manometry, endoanal ultrasound
Starting date	January 2000
Contact information	Sonia Stott
Notes	

DATA AND ANALYSES

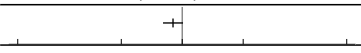
Comparison 1. Anal sphincter exercises/PFMT with or without biofeedback versus no treatment

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Number of people failing to achieve full continence (worse, unchanged or improved)	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
2 Number of people with no improvement in incontinence status (worse or unchanged)	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
3 Number of incontinence episodes per week	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
4 Number of pad changes required per week	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
5 Incontinence score	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
6 Number of people with adverse effects	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
7 Number of people dissatisfied with the treatment	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
8 Sensory threshold (rectal balloon distension - ml)	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
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 General health measures	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
14 Condition specific quality of life measures	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
15 Psychological health measures	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
16 Activities of daily living measures	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]

Analysis 1.1. Comparison 1 Anal sphincter exercises/PFMT with or without biofeedback versus no treatment, Outcome 1 Number of people failing to achieve full continence (worse, unchanged or improved).

Study or subgroup	Exercises or BF n/N	No exercises or BF n/N	Risk Ratio M-H, Fixed, 95% CI	Risk Ratio M-H, Fixed, 95% CI
Miner 1990	9/13	12/12		0.71[0.48,1.03]

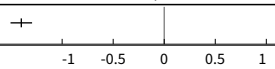


Analysis 1.2. Comparison 1 Anal sphincter exercises/PFMT with or without biofeedback versus no treatment, Outcome 2 Number of people with no improvement in incontinence status (worse or unchanged).

Study or subgroup	Exercises or BF n/N	No exercises or BF n/N	Risk Ratio M-H, Fixed, 95% CI	Risk Ratio M-H, Fixed, 95% CI
Miner 1990	2/13	7/12		0.26[0.07,1.03]

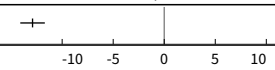
Analysis 1.3. Comparison 1 Anal sphincter exercises/PFMT with or without biofeedback versus no treatment, Outcome 3 Number of incontinence episodes per week.

Study or subgroup	Exercises or BF		No exercises or BF		Mean Difference	Mean Difference
	N	Mean(SD)	N	Mean(SD)	Fixed, 95% CI	Fixed, 95% CI
Miner 1990	13	0.9 (0.1)	12	2.3 (0.2)		-1.4[-1.51,-1.29]



Analysis 1.8. Comparison 1 Anal sphincter exercises/PFMT with or without biofeedback versus no treatment, Outcome 8 Sensory threshold (rectal balloon distension - ml).

Study or subgroup	Exercises or BF		No exercises or BF		Mean Difference	Mean Difference
	N	Mean(SD)	N	Mean(SD)	Fixed, 95% CI	Fixed, 95% CI
Miner 1990	13	6.6 (0.6)	12	19.5 (2.1)		-12.9[-14.1,-11.7]



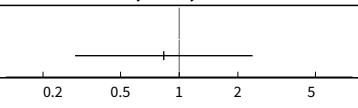
Comparison 2. Anal sphincter exercises/PFMT with or without biofeedback versus any other treatment alone

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Number of people failing to achieve full continence (worse, unchanged or improved)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
2 Number of people with no improvement in incontinence status (worse or unchanged)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
3 Number of incontinence episodes per week	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
4 Number of pad changes required per week	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
5 Incontinence score	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
6 Number of people with adverse effects	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
7 Number of people dissatisfied with the treatment	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
7.1 Biofeedback vs electrical stimulation	1		Risk Ratio (M-H, 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]

Outcome or subgroup title	No. of studies	No. of participants	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 General health measures	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
14 Condition specific quality of life measures	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
15 Psychological health measures	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
16 Activities of daily living measures	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]

Analysis 2.7. Comparison 2 Anal sphincter exercises/PFMT with or without biofeedback versus any other treatment alone, Outcome 7 Number of people dissatisfied with the treatment.

Study or subgroup	Exercises +/- BFB n/N	Other treatment n/N	Risk Ratio M-H, Fixed, 95% CI	Risk Ratio M-H, Fixed, 95% CI
2.7.1 Biofeedback vs electrical stimulation				
Naimy 2007	5/25	6/25		0.83[0.29,2.38]



Comparison 3. Anal sphincter exercises/PFMT with or without biofeedback and another treatment versus any other treatment alone

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Number of people failing to achieve full continence (worse, unchanged or improved)	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
1.1 Exercises +BF+ ES vs ES alone	1		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
2 Number of people with no improvement in incontinence status (worse or unchanged)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
3 Satisfaction with the treatment	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
4 Number of incontinence episodes per week	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
4.1 Exercises + drugs vs SNS	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
5 Number of pad changes required per week	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
5.1 Exercises + drugs vs SNS	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
6 Incontinence score	3		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
6.1 Exercises + BF + surgery vs surgery alone	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
6.2 Exercises + drugs vs SNS	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
6.3 Exercises + BF + ES vs ES alone	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
7 Number of people with adverse effects	0	0	Risk Ratio (M-H, 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	0		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
9.1 Exercises + BF + ES vs ES alone	0		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
10 Manometric squeeze pressure (cm of water)	0		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
10.1 Exercises + BF + ES vs ES alone	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]

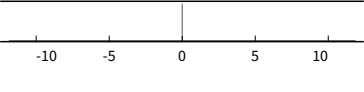
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
15 General health measures	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
15.1 Exercises + drugs vs SNS	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
16 Condition specific quality of life measures	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
16.1 Exercises + drugs vs SNS	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
17 Psychological health measures	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
17.1 Exercises + drugs vs SNS	1		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]
19 Satisfaction with treatment (VAS)	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
19.1 Exercises + BF + surgery vs surgery alone	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
20 Manometric pressures (medians)			Other data	No numeric data
20.1 Exercises + BF + education vs exercises + education			Other data	No numeric data

Analysis 3.1. Comparison 3 Anal sphincter exercises/PFMT with or without biofeedback and another treatment versus any other treatment alone, Outcome 1 Number of people failing to achieve full continence (worse, unchanged or improved).

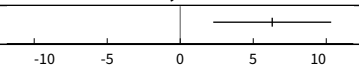
Study or subgroup	Exercises +/- BF + other n/N	Other alone n/N	Risk Ratio M-H, Fixed, 95% CI	Risk Ratio M-H, Fixed, 95% CI
3.1.1 Exercises +BF+ ES vs ES alone				
Schwandner 2011	18/39	41/41		0.47[0.33,0.65]

Analysis 3.4. Comparison 3 Anal sphincter exercises/PFMT with or without biofeedback and another treatment versus any other treatment alone, Outcome 4 Number of incontinence episodes per week.

Study or subgroup	Exercises +/- BF + other N	Mean(SD)	Other alone N	Mean(SD)	Mean Difference Fixed, 95% CI	Mean Difference Fixed, 95% CI
3.4.1 Exercises + drugs vs SNS						

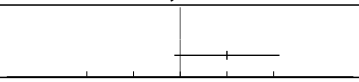


Study or subgroup	Exercises +/- BF + other		Other alone		Mean Difference	Mean Difference
	N	Mean(SD)	N	Mean(SD)	Fixed, 95% CI	Fixed, 95% CI
Tjandra 2008	60	9.4 (11.8)	53	3.1 (10.1)		6.3[2.26,10.34]



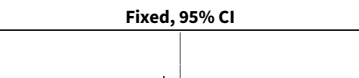
Analysis 3.5. Comparison 3 Anal sphincter exercises/PFMT with or without biofeedback and another treatment versus any other treatment alone, Outcome 5 Number of pad changes required per week.

Study or subgroup	Exercises +/- BF + other		Other alone		Mean Difference	Mean Difference
	N	Mean(SD)	N	Mean(SD)	Fixed, 95% CI	Fixed, 95% CI
3.5.1 Exercises + drugs vs SNS						
Tjandra 2008	60	3.2 (3.1)	53	2.2 (3)		1[-0.13,2.13]



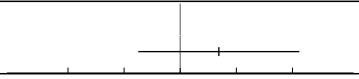
Analysis 3.6. Comparison 3 Anal sphincter exercises/PFMT with or without biofeedback and another treatment versus any other treatment alone, Outcome 6 Incontinence score.

Study or subgroup	Exercises +/- BF + other		Other alone		Mean Difference	Mean Difference
	N	Mean(SD)	N	Mean(SD)	Fixed, 95% CI	Fixed, 95% CI
3.6.1 Exercises + BF + surgery vs surgery alone						
Davis 2004	14	7.4 (4.6)	17	9.1 (4.9)		-1.75[-5.1,1.6]
3.6.2 Exercises + drugs vs SNS						
Tjandra 2008	60	14.1 (1.9)	53	1.2 (1.8)		12.9[12.22,13.58]
3.6.3 Exercises + BF + ES vs ES alone						
Schwandner 2011	39	3.8 (5)	41	12.6 (3.5)		-8.8[-10.7,-6.9]



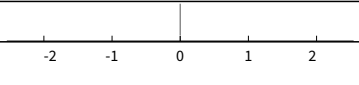
Analysis 3.15. Comparison 3 Anal sphincter exercises/PFMT with or without biofeedback and another treatment versus any other treatment alone, Outcome 15 General health measures.

Study or subgroup	Exercises +/- BF + other		Other alone		Mean Difference	Mean Difference
	N	Mean(SD)	N	Mean(SD)	Fixed, 95% CI	Fixed, 95% CI
3.15.1 Exercises + drugs vs SNS						
Tjandra 2008	60	-40.5 (10.2)	53	-42.2 (9.3)		1.72[-1.87,5.31]

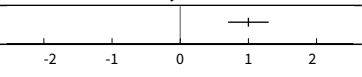


Analysis 3.16. Comparison 3 Anal sphincter exercises/PFMT with or without biofeedback and another treatment versus any other treatment alone, Outcome 16 Condition specific quality of life measures.

Study or subgroup	Exercises +/- BF + other		Other alone		Mean Difference	Mean Difference
	N	Mean(SD)	N	Mean(SD)	Fixed, 95% CI	Fixed, 95% CI
3.16.1 Exercises + drugs vs SNS						

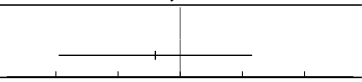


Study or subgroup	Exercises +/- BF + other N	Mean(SD)	Other alone N	Mean(SD)	Mean Difference Fixed, 95% CI	Mean Difference Fixed, 95% CI
Tjandra 2008	60	-2.3 (0.9)	53	-3.3 (0.7)		1[0.7,1.3]



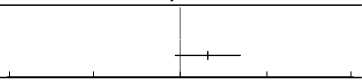
Analysis 3.17. Comparison 3 Anal sphincter exercises/PFMT with or without biofeedback and another treatment versus any other treatment alone, Outcome 17 Psychological health measures.

Study or subgroup	Exercises +/- BF + other N	Mean(SD)	Other alone N	Mean(SD)	Mean Difference Fixed, 95% CI	Mean Difference Fixed, 95% CI
3.17.1 Exercises + drugs vs SNS						
Tjandra 2008	60	48.2 (10.1)	53	49.2 (10.9)		-1[-4.89,2.89]



Analysis 3.19. Comparison 3 Anal sphincter exercises/PFMT with or without biofeedback and another treatment versus any other treatment alone, Outcome 19 Satisfaction with treatment (VAS).

Study or subgroup	Exercises +/- BF + other N	Mean(SD)	Other alone N	Mean(SD)	Mean Difference Fixed, 95% CI	Mean Difference Fixed, 95% CI
3.19.1 Exercises + BF + surgery vs surgery alone						
Davis 2004	14	8 (2.5)	17	6.4 (2.9)		1.59[-0.31,3.49]



Analysis 3.20. Comparison 3 Anal sphincter exercises/PFMT with or without biofeedback and another treatment versus any other treatment alone, Outcome 20 Manometric pressures (medians).

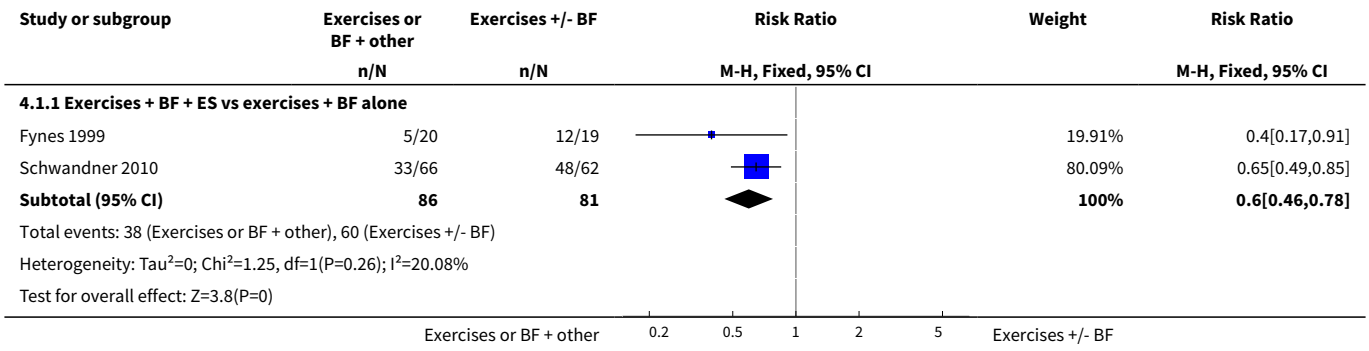
Study	Manometric pressures (medians) Resting pressure	Squeeze pressure	Fatigue time
		Exercises + BF + education vs exercises + education	
Ilnyckyj 2005	Education plus = 51.6 (mm [H2O]) Control (education) = 34.1 (mm [H2O])	Education plus BF = 91.7 (mm [H2O]) Control = 81.3 (mm [H2O])	Treatment = 19.4 Control = 14.0

Comparison 4. Anal sphincter exercises/PFMT with or without biofeedback and another treatment versus exercises with or without biofeedback

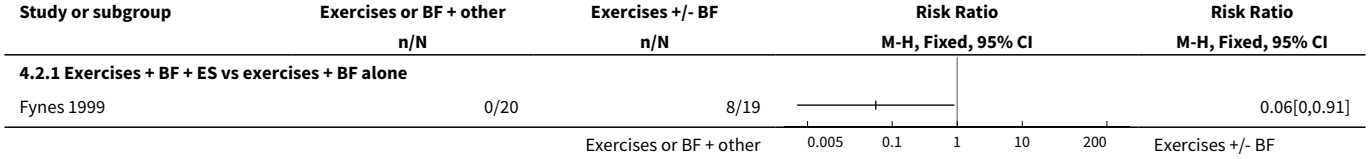
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Number of people failing to achieve full continence (worse, unchanged or improved)	2		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
1.1 Exercises + BF + ES vs exercises + BF alone	2	167	Risk Ratio (M-H, Fixed, 95% CI)	0.60 [0.46, 0.78]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2 Number of people with no improvement in incontinence status (worse or unchanged)	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
2.1 Exercises + BF + ES vs exercises + BF alone	1		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
3 Number of people dissatisfied with the treatment	0	0	Risk Ratio (M-H, 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	1		Mean Difference (IV, Random, 95% CI)	Totals not selected
6.1 Exercises + BF + ES vs exercises + BF alone	1		Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
7 Number of people with adverse effects	0	0	Risk Ratio (M-H, 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]

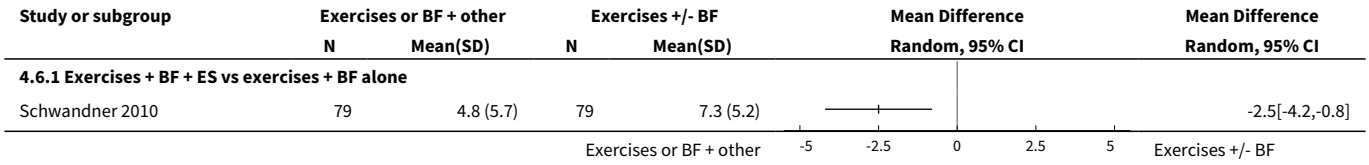
Analysis 4.1. Comparison 4 Anal sphincter exercises/PFMT with or without biofeedback and another treatment versus exercises with or without biofeedback, Outcome 1 Number of people failing to achieve full continence (worse, unchanged or improved).



Analysis 4.2. Comparison 4 Anal sphincter exercises/PFMT with or without biofeedback and another treatment versus exercises with or without biofeedback, Outcome 2 Number of people with no improvement in incontinence status (worse or unchanged).



Analysis 4.6. Comparison 4 Anal sphincter exercises/PFMT with or without biofeedback and another treatment versus exercises with or without biofeedback, Outcome 6 Incontinence score.



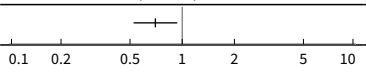
Comparison 5. Anal sphincter exercises/PFMT and biofeedback versus anal sphincter exercises/PFMT alone

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Number of people failing to achieve full continence (worse, unchanged or improved)	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
2 Number of people with no improvement in incontinence status (worse or unchanged)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3 Number of people dissatisfied with the treatment	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
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 effects	0	0	Risk Ratio (M-H, 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]

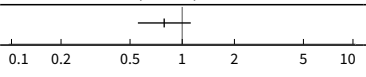
Analysis 5.1. Comparison 5 Anal sphincter exercises/PFMT and biofeedback versus anal sphincter exercises/ PFMT alone, Outcome 1 Number of people failing to achieve full continence (worse, unchanged or improved).

Study or subgroup	Exercises and BF n/N	Exercises alone n/N	Risk Ratio M-H, Fixed, 95% CI	Risk Ratio M-H, Fixed, 95% CI
Heymen 2009	25/45	50/63		0.7[0.52,0.94]



Analysis 5.3. Comparison 5 Anal sphincter exercises/PFMT and biofeedback versus anal sphincter exercises/PFMT alone, Outcome 3 Number of people dissatisfied with the treatment.

Study or subgroup	Exercises and BF n/N	Exercises alone n/N	Risk Ratio M-H, Fixed, 95% CI	Risk Ratio M-H, Fixed, 95% CI
Heymen 2009	21/41	41/63		0.79[0.56,1.12]



Comparison 6. One type of biofeedback versus another type of biofeedback

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Number of people failing to achieve full continence (worse, unchanged or improved)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
2 Number of people with no improvement in incontinence status (worse or unchanged)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
3 Number of people dissatisfied with the treatment	0	0	Risk Ratio (M-H, 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 Incontinence score (median)			Other data	No numeric data
8 Number of people with adverse effects	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
9 Sensory threshold (rectal balloon distension - ml)	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
10 Manometric resting pressure (cm of water)	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]

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

Analysis 6.7. Comparison 6 One type of biofeedback versus another type of biofeedback, Outcome 7 Incontinence score (median).

	Incontinence score (median)		
Study	St Marks Vaizey 0-13	Pescatori (0-6)	Self-rating (0-10)
Solomon 2003	Ultrasound BFB = 7 Manometric = 6 Exercises only = 8	Ultrasound BFB = 4 Manometric BFB = 4 Exericses alone = 4	Ultrasound BFB = 3.6 Manometric BFB = 4.0 Exericses alone = 3.5

Analysis 6.13. Comparison 6 One type of biofeedback versus another type of biofeedback, Outcome 13 Manometric pressures (medians).

	Manometric pressures (medians)		
Study	Resting pressure	Squeeze pressure	Fatigue time
Solomon 2003	Ultrasound BFB = 44 (mm Hg) Manometric BFB = 45 (mm Hg) Exericses alone = 48	Ultrasound BFB = 95 (mm Hg) Manometric BFB = 78 (mm Hg) Exericses alone = 90	Ultrasound BFB = 27 (sec) Manometric BFB = 21 (sec) Exericses alone = 15

Comparison 7. One type of anal sphincter exercises/PFMT versus another type of anal sphincter exercises/ PFMT

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Number of people failing to achieve full continence (worse, unchanged or improved)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
2 Number of people with no improvement in incontinence status (worse or unchanged)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
3 Number of incontinence episodes per week	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
4 Number of pad changes required per week	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
5 Incontinence score	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
6 Number of people with adverse effects	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
7 Number of people dissatisfied with the treatment	0	0	Risk Ratio (M-H, 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 General health measures	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
14 Condition specific quality of life measures	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
15 Psychological health measures	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
16 Activities of daily living measures	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]

WHAT'S NEW

Date	Event	Description
23 April 2012	New search has been performed	Substantive amendment: updated with nine new studies and conclusions changed.
23 April 2012	New citation required and conclusions have changed	updated with nine new studies.

HISTORY

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

Date	Event	Description
16 September 2008	Amended	Converted to new review format.
24 May 2006	New search has been performed	For this update six published studies were added to the previous review (Davis 2004; Heymen 2000; Ilnyckyj 2005; Mahony 2004; Norton 2003; Solomon 2003).
23 May 2006	New citation required and conclusions have changed	Substantive amendment

CONTRIBUTIONS OF AUTHORS

One review author (C Norton) wrote the initial protocol of the review. Both review authors independently assessed the pertinence and quality of eligible studies and selected which to include in the review. Two review authors independently extracted data from trial reports of identified studies and both interpreted the results and contributed to the writing of the final version of the review.

DECLARATIONS OF INTEREST

The lead review author is an author of a study included in the review.

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)

*Anal Canal; Combined Modality Therapy [methods]; Electric Stimulation Therapy [*methods]; Exercise Therapy [*methods]; Fecal Incontinence [*therapy]; Feedback, Sensory [*physiology]; Pelvic Floor; Randomized Controlled Trials as Topic; Treatment Outcome

MeSH check words

Adult; Female; Humans; Male