Conservative management for postprostatectomy urinary incontinence (Review)

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[Intervention Review]

Conservative management for postprostatectomy urinary incontinence

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ABSTRACT

Background

Urinary incontinence is common after both radical prostatectomy (RP) and transurethral resection of the prostate (TURP). Conservative management includes pelvic floor muscle training (PFMT) with or without biofeedback, electrical stimulation, compression devices (penile clamps), lifestyle changes, extra-corporeal magnetic innervation or a combination of methods.

Objectives

To assess the effects of conservative management for urinary incontinence after prostatectomy.

Search methods

We searched the Cochrane Incontinence Group Specialised Trials Register (searched 23 January 2006), MEDLINE (January 1966 to January 2006), EMBASE (January 1988 to January 2006), CINAHL (January 1982 to January 2006), PsycLIT (January 1984 to January 2006), ERIC (January 1984 to January 2006), the reference lists of relevant articles, handsearched conference proceedings and contacted investigators to locate studies.

Selection criteria

Randomised or quasi-randomised controlled trials evaluating conservative interventions for urinary continence after prostatectomy.

Data collection and analysis

At least two review authors assessed the methodological quality of trials and abstracted data.

Main results

Seventeen trials met the inclusion criteria, fifteen trials amongst men after radical prostatectomy (RP), one trial after transurethral resection of the prostate (TURP) and one trial after either operation. There was considerable variation in the interventions, populations and outcome measures. The majority of trials in this area continue to be of moderate quality, although more recent studies have been of higher quality in terms of both randomisation and blinding. Data were not available in all the trials for many of the pre-stated outcomes. Confidence intervals have tended to be wide except for the more recent studies, and it continues to be difficult to reliably identify or rule out a useful effect.

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There were several important variations in the populations being studied. Therefore the decision was made by the review authors to separate in the analysis the men having the intervention as prevention (whether administered before or after operation, to all men having surgery) or as treatment (postoperatively to those men who did have urinary incontinence), as well as separating those treated with TURP or RP.

Amongst seven treatment trials of postoperative PFMT for urinary incontinence after RP, one trial suggested benefits, whereas the estimates from the others were consistent with no effect. There was clinical and statistical heterogeneity, precluding meta-analysis. There was no clear reason for this heterogeneity. Trials of preventative PFMT started pre or post-operatively also showed heterogeneity: only one large trial favoured PFMT but the data from the others were conflicting.

Analysis of other conservative interventions such as transcutaneous electrical nerve stimulation and anal electrical stimulation, or combinations of these interventions were inconclusive. There were too few data to determine treatment effects on incontinence after TURP. The findings should continue to be treated with caution, as most studies were of poor to moderate quality.

With respect to other management, men in one trial reported a preference for one type of external compression device compared to two others or no treatment. The effect of other conservative interventions such as lifestyle changes remains undetermined as no trials involving these interventions were identified. Men's symptoms tended to improve over time, irrespective of management.

Authors' conclusions

The value of the various approaches to conservative management of postprostatectomy incontinence remains uncertain. Long-term incontinence may be managed by external penile clamp, but there are safety problems.

PLAIN LANGUAGE SUMMARY

Conservative management for men with urinary incontinence after prostate surgery

The prostate is a male sex gland that surrounds the outlet of the bladder. Two main diseases of the prostate (cancer of the prostate, or benign prostatic enlargement) can be treated by surgery but some men suffer leakage of urine (urinary incontinence) afterwards. Conservative treatment of the leakage, such as pelvic floor muscle training with or without biofeedback or anal electrical stimulation are thought to help men control this leakage. The review of trials found that there was conflicting information about the benefit of pelvic floor muscle training for either prevention or treatment of urine leakage after prostate surgery, whether for cancer or benign (non cancerous) enlargement of the prostate (endoscopic resection). Of three external compression devices tested, one type seemed to be better than the others but needs to be used cautiously because of safety risks. More research of better quality is needed to assess conservative managements.

BACKGROUND

It is not uncommon for men to have urinary incontinence (UI) after prostatectomy. The reported frequency varies depending on the type of surgery and surgical technique (Grise 2001; Peyromaure 2002), the definition and quantification of incontinence (Grise 2001; Peyromaure 2002), the timing of the evaluation relative to the surgery, and who evaluates the presence or absence of incontinence (physician or patient) (Donnellan 1997; McCammon 1999). Reported prevalence rates of UI after radical prostatectomy (RP) for prostate cancer vary from 5% to over 60% (Hunskaar 2002). For example, in one study at three months after RP (Donnellan 1997), 51% were subjectively wet (self-report) but 36% were wet on pad testing (objective). By 12 months, 20% were subjectively still wet, but only 16% were classed as wet using objective criteria. After transurethral resection of the prostate (TURP) for benign prostate disease, UI is less common at three months after operation (e.g. 10% needing to wear pads), but longer term data are not available (Emberton 1996).

After both types of operation, the problem tends to improve with time: it declines and plateaus within one to two years postoperatively (Hunskaar 2002). However, some men are left with incontinence that persists for years afterwards.

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Continence mechanisms

Urinary continence depends on a complex interaction of smooth and striated muscle fibres blended together to form the continence mechanism. Considerable debate has existed in the literature as to whether incontinence after prostatectomy is due to an effect on the detrusor (bladder) muscle or on the sphincter, as commonly these abnormalities coexist (Peyromaure 2002). New detrusor overactivity and intrinsic sphincter deficiency due to sphincteric injury (Ficazzola 1998; Groutz 2000; McGuire 1990) or weakness (Majoros 2006) are cited as the most important causes of persistent incontinence after RP. Debate continues on whether detrusor overactivity is a primary or secondary factor. Whereas some report overactivity as the primary cause of postprostatectomy incontinence (Golubuff 1995; Leach 1995) others argue strongly that even if other factors play a role, intrinsic sphincter deficiency is the primary cause of UI after RP (Aboseif 1996; Chao 1995; Groutz 2000; Gudziak 1996; Kondo 2002; Majoros 2006; Winters 1997). Risk factors for postprostatectomy UI after RP include pre-existing abnormalities of detrusor contractility (Leach 1995) and older age (Diokno 1997; Kondo 2002) (possibly due to progressive reduction in sphincter striated muscle cells with age, (Strasser 1997)). Other risk factors include previous TURP (Jacobsen 2007); preoperative radiotherapy (Kondo 2002; Rainwater 1988); trauma; spinal cord lesion; new obstruction due to recurrence, bladder neck contracture, or urethral stricture (Litwiller 1997); Parkinson's disease (Kondo 2002); dementia; and medications (Khan 1991). A surgeon's inadequate skill and expertise (Eastham 1996) and having surgery in a hospital which performs fewer than 20 radical prostatectomies a year may also be a factor (Albertsen 1997).

After TURP, UI is thought to most likely be due to pre-existing abnormalities of bladder function such as poor compliance or detrusor overactivity, rather than direct sphincter injury (Abrams 1991), possibly because removal of the prostatic tissue removed some of the protective mechanism for continence.

The treatments recommended for postprostatectomy UI are usually 'conservative,' not involving drugs or surgery. Six categories of conservative management are considered in this review, singly and in combination when appropriate.

1. Pelvic floor muscle training (PFMT)

This involves any method of training the pelvic floor muscles to contract, including teaching performance of an accurate voluntary pelvic floor muscle contraction using biofeedback, and coordinating and timing the contraction against increases in intra-abdominal pressure, often called functional PFMT.

Traditionally, biofeedback involves the use of equipment to provide visual or auditory feedback about the pelvic floor muscle function to enable one to train, strengthen and increase endurance and coordination of the pelvic floor muscle contractions. Simple auditory biofeedback can also be provided by the therapist informing the patient when a contraction is felt through digital anal examination during the pelvic floor muscle contraction.

The theoretical basis of PFMT is that repeated, volitional contractions of selected pelvic floor muscles may improve their strength and efficiency during periods of increased intra-abdominal pressure. In a systematic review of the literature on female UI, Berghmans and colleagues noted that a pelvic floor muscle contraction may raise the urethra and press it towards the symphysis pubis, prevent urethral descent, and improve structural support of the pelvic organs (Berghmans 1998). They further pointed out that PFMT may result in hypertrophy of the periurethral striated muscles thereby increasing the 'external mechanical pressure on the urethra'.

2. Electrical stimulation (non-invasive) delivered via surface electrodes.

- Anal electrical stimulation

Any type of electrical stimulation using a non-invasive surface anal probe designed for the therapy. The intention of electrical stimulation is to facilitate contraction of the periurethral striated muscle.

- Sticky patch electrodes, also called transcutaneous electrical nerve stimulation (TENS).

Transcutaneous electrical nerve stimulation is a low intensity, sensory nerve stimulation used for detrusor overactivity, delivered at various sites, using patch electrodes. Sites include the sacral dermatomes (Hasan 1996), dorsal penile nerve (Nakamura 1984), hamstring and quadriceps muscle (Okada 1998), and the posterior tibial or perineal nerves (McGuire 1983).

3. Lifestyle adjustment

This includes fluid adjustment, diet, caffeine elimination, physical exercise, weight loss and cessation of smoking.

4. Extra-corporeal magnetic innervation

This involves the use of a magnetic chair to stimulate contraction of the pelvic floor muscles (Galloway 2000).

5. External penile compression devices

These devices use an external clamp to achieve non-surgical compression of the urethra.

The initial review on the topic of postprostatectomy UI, first published in 1999 (Moore 1999b) and updated in 2001 (Moore 2001), only considered post operative PFMT, biofeedback and electrical stimulation. In the last update (Hunter 2004), the review was broadened to include studies evaluating lifestyle adjustment, external penile compression devices and extracorporeal magnetic innervation. The current update includes studies on men after TURP.

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OBJECTIVES

To determine the effects of conservative management for UI after transurethral, suprapubic, laparoscopic, radical retropubic or perineal prostatectomy, including any single conservative therapy or any combination of conservative therapies. Pharmacological agents will be considered in separate reviews. The use of the term 'sham therapy' in this review means any therapy that could not influence the pelvic floor muscles such as placing an electrical stimulation probe in the anus but not turning it on.

The following comparisons were made for treatment and/or prevention of UI after prostatectomy:

Radical prostatectomy

Treatment (of incontinent men, after surgery)

(1) post-operative PFMT with or without biofeedback versus no treatment or sham therapy or verbal instruction;
(2) post-operative interventions using electric or magnetic energy (e.g. post-operative anal electrical stimulation, perineal electrical stimulation, transcutaneous electrical nerve stimulation (TENS), extracorporeal magnetic innervation (ExMI)) versus no treatment or sham treatment;
(3) post-operative lifestyle adjustment versus no treatment or sham treatment;
(4) post-operative combinations of treatments versus no treatment or sham treatment;
(5) post-operative use of one treatment versus another active treatment;

Prevention (of UI in all men having surgery, intervention before and/or after prostatectomy)

(6) pre or post-operative PFMT with or without biofeedback versus no treatment or sham therapy or verbal instruction;
(7) pre or post-operative interventions using electric or magnetic energy (e.g. post-operative anal electrical stimulation, perineal electrical stimulation, transcutaneous electrical nerve stimulation (TENS), extracorporeal magnetic innervation (ExMI)) versus no treatment or sham treatment;
(8) pre or post-operative lifestyle adjustment versus no treatment or sham treatment;
(9) pre or post-operative combinations of treatments versus no treatment or sham treatment;
(10) pre or post-operative use of one treatment versus another active treatment;

TURP

Treatment (of incontinent men, after surgery)

(11) post-operative PFMT with or without biofeedback versus no treatment or sham therapy or verbal instruction;
(12) post-operative interventions using electric or magnetic energy (e.g. post-operative anal electrical stimulation, perineal electrical stimulation, transcutaneous electrical nerve stimulation (TENS), extracorporeal magnetic innervation (ExMI)) versus no treatment or sham treatment;
(13) post-operative lifestyle adjustment versus no treatment or sham treatment;
(14) post-operative combinations of treatments versus no treatment or sham treatment;
(15) post-operative use of one treatment versus another active treatment;

Prevention (of UI in all men having surgery, intervention before and/or after prostatectomy)

(16) pre or post-operative PFMT with or without biofeedback versus no treatment or sham therapy or verbal instruction;
(17) pre or post- operative interventions using electric or magnetic energy (e.g. post-operative anal electrical stimulation, perineal electrical stimulation, transcutaneous electrical nerve stimulation (TENS), extracorporeal magnetic innervation (ExMI)) versus no treatment or sham treatment;
(18) pre or post-operative lifestyle adjustment versus no treatment or sham treatment;
(19) pre or post-operative combinations of treatments versus no treatment or sham treatment;
(20) pre or post-operative use of one treatment versus another active treatment;

Containment

(21) external penile compression devices (penile clamps) versus no treatment or sham treatment.
We have not listed all possible comparisons here. As and when new trials address new comparisons these will be added to the review.

METHODS

Criteria for considering studies for this review

Types of studies

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Randomised or quasi-randomised controlled trials of conservative management to prevent or treat UI after TURP or RP were sought.

Types of participants

Men undergoing a prostatectomy for either benign prostatic hyperplasia or prostate cancer. Studies involving men experiencing UI prior to prostatectomy were excluded.

Types of interventions

PFMT; biofeedback (verbal or machine-mediated); electrical stimulation via a surface electrode (e.g. anal probe electrical stimulation; sticky patch electrode; transcutaneous electrical nerve stimulation (TENS)); extra-corporeal magnetic innervation (ExMI); lifestyle adjustment; and external penile compression devices. These interventions can be compared with no treatment or with each other, alone or in combination.

Types of outcome measures

Primary outcomes:

1. Patient reported symptoms

- Self report of UI (number not cured or improved)
- Number of pad/clothing changes (pad changes per 24 hours)
- Frequency of UI from self-report or diary (incontinent episodes per 24 hours)
- Frequency of micturitions per 24 hours
- De novo urge symptoms

2. Objective Measures

- Standardised pad test (24 hour or 1 hour) measuring grams of urine lost

Secondary outcomes:

1. Patient satisfaction

- Self report of satisfaction with method

2. Health status measures

- Impact of UI e.g. Incontinence Impact Questionnaire (Uebersax 1995)
- General health status e.g. Short Form 36 (Ware 1993)
- Quality of life e.g. European Organisation for Research and Treatment of Cancer (EORTC QLQ-C30), version 2 (Aaronson 1988; Aaronson 1993)
- Symptom inventory e.g. International Prostate Symptom Score (IPSS) (Barry 1992)

3. Adverse events due to treatment

4. Health economics

- Cost of intervention
- Resource implications of differences in outcome
- Economic analysis (cost effectiveness, cost utility)

5. Other outcomes

- Non pre-specified outcomes judged important when performing the review.

Search methods for identification of studies

This review has drawn on the search strategy developed for the Incontinence Review Group. Relevant trials were identified from the Group's Specialised Register of controlled trials which is described, along with the group's search strategy, under the Incontinence Group's details in *The Cochrane Library* (For more details please see the 'Specialized Register' section of the Group's module in The Cochrane Library). The register contains trials identified from MEDLINE, CINAHL, the Cochrane Central Register of Controlled Trials (CENTRAL) and hand searching of journals and conference proceedings. The Incontinence Group Specialised Trials Register was searched using the Group's own keyword system, the search terms used were:
({design.cct*} OR {design.rct*})
AND
({topic.urine.incon.postprost*})
(All searches were of the keyword field of Reference Manager 9.5 N, ISI ResearchSoft).
Date of the most recent search of the register for this review: 23 January 2006.
The trials in the Incontinence Group Specialised Register are also contained in CENTRAL.
Extra specific searches were also performed. These are detailed below.

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Systematic searches of electronic bibliographic databases

The following electronic bibliographic databases were searched (date search was performed: 10 January 2006):
MEDLINE - dates searched: January 1966 to January 2006;
EMBASE - dates searched: January 1988 to January 2006;
PsycLIT - dates searched: January 1984 to January 2006;
CINAHL - dates searched: January 1982 to January 2006;
ERIC - dates searched: January 1984 to January 2006.
The following search terms were used in each database (no limits were applied to the searches):
incontinence, urinary, male, postprostatectomy, stimulation, electrical stimulation, biofeedback, pelvic muscle exercises, Kegel exercises, behavioural, behaviour, behavior, therapy, behaviour modification, therapy, physiotherapy, lifestyle, weight loss, caffeine, smoking, extracorporeal magnetic innervation, external penile compression devices, continence, bladder control, quality of life, randomised (randomized) controlled trial, evaluation, effectiveness, efficacy, outcomes.

Handsearching of conference proceedings

The following conference proceedings were handsearched:

- American Urological Association (years searched: 1989-2005) Supplement to the Journal of Urology, published as a supplement.
- Society of Urologic Nurses and Associates (SUNA) (formerly American Urologic Association Allied) these abstracts are not published but are available in the SUNA office. Annual meeting (years searched: 1991 to 2003);1991-Las Vegas, NV; 1992-Washington, DC; 1993-San Antonio, TX; 1994-San Francisco, CA; 1995-Las Vegas,NV; 1996-Orlando, FL, 1997-New Orleans, LA. Biannual incontinence meeting: 1992-Tampa, Fla (1st meeting), 1994-Phoenix, 1996-Dallas, 1998-Orlando, 2000-Nashville, 2004-Chicago, 2006-NYC; Understanding urodynamics seminar:1993-Denver, CO; 1994-San Antonio, TX; 1995-Cleveland, OH; 1996-St Louis, MO.
- Wound Ostomy and Continence Nurses (years searched: 1996, 1997,1999 to 2006). Annual meeting: 1996- Seattle, WA; 1997-Nashville, TN; Incontinence meeting (biannual); 1997-Beverly Hills (1st meeting); 1999-Austin, TX. (No further Incontinence meetings.)
- International Continence Society (years searched: 1980 to 2006). Published proceedings in Neurourology and Urodynamics.

Reference lists of relevant articles

The reference lists of relevant articles were searched for other possibly relevant trials.

Contact with investigators in the field

Investigators were contacted to ask for other possibly relevant trials, published or unpublished.
No language or other limits were imposed on the searches.

Data collection and analysis

The methodological quality of the trials was assessed using the Cochrane Incontinence Group's criteria presented in the The Cochrane Library. The Group's assessment tool is not scored. The following methodological parameters are included:
1) identification of study as randomised or quasi-randomised;
2) description of inclusion/exclusion criteria;
3) potential for selection bias (quality of random allocation concealment) rating;
4) potential for bias around time of treatment or during outcome assessment (blinding) rating;
5) potential for selection bias in analysis (description of withdrawals/dropouts/lost to follow up, analysis on intention to treat);
6) appropriate statistical analysis.
For the initial review (1999) and first update (2001), methodological quality assessment was performed by two review authors (KNM, DJC) using standard Cochrane methods. For the second (2001) and third update (2004) similar approaches were used.
The list of abstracts was reviewed independently by two review authors (KFH and KNM) and results compared. The full text article of references or abstracts identified as potentially relevant by either reviewer were retrieved and reviewed by both. Reference lists of relevant review articles were reviewed to identify any further trials. References were assessed based on the population, interventions, control management, outcomes and overall study design. Using the full text of the potentially relevant published studies and abstracts, the same two review authors (KFH and KNM) independently reviewed the studies for relevance and inclusion. Authors were contacted for further data and/or clarification of methods. One review author (KFH) also reassessed the quality of trials included in the previous versions of the reviews (1999 - 2001). Disagreements were resolved through discussion; third party arbitration was not required.
Data for the trials added to the 2004 and 2006 updates were extracted independently by two reviewers (KFH and KNM) using a standard form developed for this purpose. The following information was included:

- study method and characteristics (design, method of randomisation, inclusion/exclusion criteria, withdrawals/dropouts);
- participants (population, age);
- type of intervention, timing and duration of therapy, co-interventions;
- control (no treatment or sham therapy or other active treatment);

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- outcomes (types of outcome measures, reported outcomes, adverse events).

Extracted data were compared by two review authors (KFH and KNM) for completeness and accuracy, and cross checked by another review author (CG). Disagreements were resolved through discussion and review of the trial report. Data were entered into Review Manager software (RevMan 4.2.3) by KFH and KNM. The data were evaluated for publication bias using graphical (i.e. funnel plot) evaluation only. This is presented in the results section.

For dichotomous outcomes, data were summarized (e.g. number of people for whom an outcome is present or not) and relative risks (RR) calculated with their 95% CIs. For continuous outcomes, each trial was summarised using the mean value for each group and SDs, and combined as weighted mean differences (WMD) if the same scale (e.g. pad test in grams of urine) was used for the outcome measurement in more than one trial. A fixed effect model was used to calculate the summary statistic and the 95% confidence intervals. Heterogeneity was assessed visually and using the Chi-squared test for heterogeneity and the I-squared statistic (Higgins 2003). Forest plots were examined and potential sources influencing heterogeneity identified. Possible sources of heterogeneity were explored statistically through subgroup analysis. Where synthesis was deemed not appropriate, a narrative overview was planned.

Comparisons of the outcomes of the chosen interventions with no treatment, with each other, and in combination were planned *a priori* for the review update. Data were not available for all planned comparisons. In planning the update, subgroup analysis based on type of surgery (RP or TURP) was planned. As there was considerable diversity in the length of time interventions were carried out and in how this time was reported, the data were further divided into categories by length of time.

Attempts were made to contact authors of trial reports if clarification was necessary. Included trial data were processed as described in the Cochrane Collaboration Handbook (Higgins 2005). Studies were excluded from the review if they made comparisons other than those pre-specified or if data were unavailable. Excluded studies are listed with reasons for their exclusion.

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies; Characteristics of ongoing studies.

For the current update (2007) sources and numbers of potentially eligible titles were Cochrane Incontinence Group Specialised Register (20), updated search of MEDLINE, EMBASE, CINAHL, PsycLIT and ERIC databases (4) and ICS proceedings (2) for a list of 26 possibly relevant articles and abstracts. After assessment 10 potentially relevant trials for addition to the review were identified. One review author (KFH) contacted five authors for further data and/or clarification of methods.

At the time of the previous update (Hunter 2004), ten trials (Bales 2000; Franke 1998; Joseph 2000; Mathewson-Chapman 97; Moore 1999; Moore 2004; Opsomer 1994; Parekh 2003; Porru 2001; van Kampen 1998) were included in the review. All involved patients who had undergone some form of RP. Four studies (Pulker 2002; Salinas Casado 1991; Salinas Casado 1996; Zermann 1999) were excluded as they were descriptive studies of conservative interventions and did not include a control group for comparison. Of these, two were English language abstracts (Pulker 2002; Zermann 1999) while the other two (Salinas Casado 1991; Salinas Casado 1996) were Spanish with an English abstract. Another study (Chang 1998) was excluded as it did not meet the criteria for random assignment to groups. A translation for one German language trial (Bocker 2002) was obtained through the Cochrane Incontinence Group but the trial was not included as the data for the postprostatectomy participants were not separated from a group of female participants who had recovered from polio. A trial (Bennett 1997) that had been included in the list of ongoing trials in the original review was excluded as it was only available in abstract and attempts to contact the author had been unsuccessful. Three additional trials identified in earlier versions of the review as ongoing (Ceresoli 2002; Griebling 1999; Nehra 2001) were excluded as they were in abstract form only with no data available, and attempts to contact the authors were unsuccessful.

For the 2006 update, in addition to the ten trials previously included in the analysis, ten potentially relevant studies on conservative management of postprostatectomy UI were identified. Five (Cornel 2005; Crevenna 2003; Ip 2004; McGlynn 2004; Seki 2005) were excluded as they did not meet the inclusion criteria. Of these, three (Cornel 2005; Crevenna 2003; Seki 2005) did not include control groups; one described an intervention not included in the study (Ip 2004); the last was a case report (McGlynn 2004). An additional study did not have data presented in a usable form (Yokoyama 2004); the authors were contacted, but no further data was available and the study was excluded.

One trial (Glazener 2004) remains ongoing.

New included trials

Seven additional trials were included in this update (Burgio 2005; Dubbelman 2004; Filocamo 2005; Floratos 2002; Hoffman 2005; Moore 2006; Wille 2003), bringing the total number of included trials to seventeen. One study previously listed as ongoing (Moore 2006) has been completed. Also, further methodological and background data was obtained from the authors of two previously excluded trials (Floratos 2002; Wille 2003), which allowed us to include these in the update.

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Types of populations

Fifteen trials involved patients undergoing RP (Bales 2000; Burgio 2005; Dubbelman 2004; Filocamo 2005; Floratos 2002; Franke 1998; Hoffman 2005; Mathewson-Chapman 97; Moore 1999; Moore 2006; Moore 2004; Opsomer 1994; Parekh 2003; van Kampen 1998; Wille 2003); one trial involved patients after TURP (Porru 2001); and one trial included patients with either TURP or RP (Joseph 2000). Participants were recruited in some trials preoperatively (Bales 2000; Burgio 2005; Mathewson-Chapman 97; Moore 2006; Parekh 2003; Wille 2003), within days or up to two weeks postoperatively (Dubbelman 2004; Filocamo 2005; Floratos 2002; Franke 1998; Hoffman 2005; Porru 2001; van Kampen 1998), or weeks to months after surgery (Joseph 2000; Moore 1999; Moore 2004; Opsomer 1994). Ten studies (Dubbelman 2004; Floratos 2002; Franke 1998; Hoffman 2005; Joseph 2000; Moore 1999; Moore 2004; Moore 2006; Opsomer 1994; van Kampen 1998) enrolled only men with post operative UI (determination of UI varied with recruitment time as above), while others included ALL men who underwent surgery (Bales 2000; Burgio 2005; Filocamo 2005; Mathewson-Chapman 97; Parekh 2003; Wille 2003). This variation in continence status may lead to different populations being studied in the trials: all undergoing surgery (many of whom are likely to recover continence spontaneously) versus those with persistent UI. The comparisons were therefore structured to reflect this: trials which included only men with postoperative incontinence were deemed to be trials of treatment, while trials in which all men were treated (irrespective of continence status) were deemed to be trials of prevention.

Types of interventions

In the included trials, there was considerable variation in the type and intensity of interventions. The duration of the treatment varied from four weeks up to one year. Three trials examined PFMT in comparison to no treatment or sham, two in post RP patients (Dubbelman 2004; Moore 1999), and one in post TURP patients (Porru 2001). Trials in which both intervention and control groups were exposed to standard pre-operative verbal or written information on pelvic muscle exercises followed by a specific PFMT protocol in the intervention group were included in this grouping. Six used PFMT with biofeedback as the intervention (Bales 2000; Franke 1998; Mathewson-Chapman 97; Moore 2006; Parekh 2003; van Kampen 1998). (Moore 1999) had a second intervention group that underwent PFMT with anal electrical stimulation. (Wille 2003) also had an intervention group that had PFMT with anal electrical stimulation, and a second intervention group with PFMT, anal electrical stimulation and biofeedback. (Opsomer 1994) used PFMT with both biofeedback and electrical stimulation of an unspecified type. (Hoffman 2005) published a three arm trial: PFMT alone, PFMT with anal electrical stimulation and PFMT with perineal electrical stimulation. In a mixed post TURP and RP group, (Joseph 2000) compared verbal feedback with machine-mediated biofeedback as a supplement to PFMT. One trial compared external penile compression devices as the intervention (Moore 2004). No trials testing lifestyle changes alone were identified.

As the populations and the type and timing of interventions varied so greatly among the studies, the decision was made by the authors to separate studies of UI prevention (pre-operative recruitment of all men undergoing surgery which included a pre-operative intervention plus or minus post-operative intervention) (Bales 2000; Burgio 2005; Filocamo 2005; Parekh 2003; Porru 2001; Mathewson-Chapman 97; Wille 2003) from those who had only post operative treatment for urinary incontinence (Dubbelman 2004; Floratos 2002; Franke 1998; Hoffman 2005; Joseph 2000; Moore 1999; Moore 2006; van Kampen 1998) or containment (Moore 2004). Studies involving post TURP patients only were also separated from those that included only RP or predominantly RP patients.

Types of outcome measures

There was lack of consistency in the reporting of outcome measures. In terms of the primary outcomes of interest in this review, only four (Joseph 2000; Mathewson-Chapman 97; Moore 2004; Moore 2006) quantified results using a pad test. Three others (Dubbelman 2004; Franke 1998; Opsomer 1994) reported using a pad test, but did not report or had incomplete data. One study (Hoffman 2005) reported results in terms of a provocative 1 hour pad test. (Floratos 2002) also used a 1 hour pad test, but (Wille 2003) used a 20 minute provocative pad test and Moore (1999) used a 24 hour pad test. Van Kampen (1998) set different limits for UI (less than 1 gram to 8 grams) and Moore 2006 set an 8 grams limit. Bladder or voiding diaries recording patient-reported symptoms of UI (the second primary outcome of interest in this review) were used in seven of the trials (Bales 2000; Franke 1998; Mathewson-Chapman 97; Moore 1999; Moore 2006; Parekh 2003; Porru 2001; van Kampen 1998). (Porru 2001) reported using the American Urological Association symptom score and a five point grading scale to assess strength of pelvic floor muscle contraction by digital evaluation. Definitions of UI, on which the number of patients remaining incontinent at the end of the trial was based, varied from the use of pads to a specified amount of urine lost. Many authors did not specify a definition of UI for their trial.

Secondary outcomes for this review pertaining to quality of life issues were included in some trials, but the findings were often provided as a narrative summary rather than numerically, and so were not available in a form suitable for statistical analysis. None reported on economic issues. Thus, none of the secondary outcomes identified for this review were included in the analysis. Five trials reported measures of quality of life or satisfaction, but they were all different measures and not reported in a format that allowed them to be included in analysis. Moore used two vali-

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dated quality of life measures (Moore 1999). Although there was a moderate correlation between one measure and the amount of urine lost, there were no differences between intervention and control groups. Satisfaction with the treatment was reported as high, based on face to face interview. (Burgio 2005) applied the Hopkins Symptom Checklist (SCL-90-R) and the Medical Outcomes Study Short Form Health Survey (SF-36), and reported no difference between intervention and control groups in terms of quality of life. (Hoffman 2005) used the QLQ-C30 and found improvement in all three groups in terms of quality of life, with most improvement occurring during the time of the rehabilitation program. (Porru 2001) used a standardized questionnaire of seven questions, some of which were open-ended allowing for written comments from participants. The intervention group was found to have a significantly higher satisfaction rate.

Risk of bias in included studies

The quality assessment criteria of the Cochrane Incontinence Group assume that the avoidance of bias is best achieved by: a randomised trial with secure concealment of allocation prior to formal entry; adequate blinding of patients, outcome assessors and health care providers; description of reasons and numbers of withdrawals and dropouts; and analysis on an intention to treat basis. None of the early trials fulfilled all these criteria. However recent trials have fared much better in terms of secure concealment of allocation and blinding.

Overall, the quality of trials included in the review was low to moderate. Although all 17 studies were identified as randomised controlled trials, only six (Burgio 2005; Hoffman 2005; Moore 1999; Moore 2004; Moore 2006; van Kampen 1998) clearly described that a technique of concealment of allocation (e.g. sealed envelopes or computerized randomisation). Blinding was not described in most of the trials, with just a handful indicating an attempt to minimize bias in intervention or outcome measurement. (Bales 2000) and (van Kampen 1998) had people not involved in provision of the intervention acting as outcomes assessors. (Moore 1999; Moore 2006 and Burgio 2005) indicated that a single therapist, blinded to control group outcomes, provided all treatment. (Bales 2000) and (Mathewson-Chapman 97) did not mention withdrawals or dropouts. All others reported the number of withdrawals or dropouts, although the reasons were not consistently reported and few, except (Moore 2006), discussed how this was dealt with in the analysis.

Effects of interventions

Radical prostatectomy: treatment of incontinent men after surgery

1. Post-operative PFMT with or without biofeedback versus no treatment or sham therapy or verbal instruction (Comparison 01)

Seven trials (Dubbelman 2004; Floratos 2002; Franke 1998; Joseph 2000; Moore 1999; Moore 2006; van Kampen 1998) have compared PFMT with or without biofeedback to no treatment (sham or verbal instruction) amongst men incontinent after RP. None of the trials had the same design making head to head comparisons difficult. Three trials (Moore 1999; Moore 2006; van Kampen 1998) taught PFMT with biofeedback and two (Floratos 2002; Franke 1998) used perineal patch EMG. In addition, four compared verbal instruction with or without written materials to structured PFMT programs of three to 24 weeks (Dubbelman 2004; Floratos 2002; Moore 1999; Moore 2006), one compared PFMT to sham PFMT (van Kampen 1998), one (van Kampen 1998) compared formal sessions of therapy to no intervention. Subjects in all treatment groups were advised to undertake daily PFMT at home. Formal PFMT post -operative sessions directed by a therapist ranged from twice a week for 12 weeks (Moore 1999), three times a week for three weeks (Floratos 2002), weekly for up to 4 (Joseph 2000) to 9 sessions (Dubbelman 2004), weekly for 24 weeks (Moore 2006) five sessions over 16 weeks (Franke 1998) or as long as the incontinence persisted (van Kampen 1998). One trial (Moore 1999) recruited subjects with persistent incontinence (some longer than one year) post-operatively, and these participants may differ from those enrolled pre-operatively (Moore 2006) or from those recruited within a week or two of catheter removal (Dubbelman 2004; Floratos 2002; van Kampen 1998) or up to 6 week post RP (Franke 1998).

Differences between trials

There was clinical heterogeneity regarding UI status at baseline, timing of recruitment and intervention, content of intervention and control treatments. The wide range of continence definitions from pad free to less than 1 gram of urine loss on pad test and high dropout rates also mean that the groups of people studied differed. Because of this heterogeneity, it was decided that data from the trials should not be used to derive summary estimates, and this should be borne in mind when interpreting the data. When the trials were considered individually, there were statistically significant differences following the intervention only in one trial (van Kampen 1998).

Number not cured

Definition of cure varied with each study: 4 grams on 24 hour pad test (Dubbelman 2004); less than 8 grams urine loss on 24 hour pad test (Moore 2006); less than 2 grams urine loss on 10 (Moore 1999) or 24 hour pad test (van Kampen 1998); or pad free (Franke 1998). One trial in particular (van Kampen 1998) favoured the treatment. The RR estimates from the other studies

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were close to 1.00, but with CIs that did not rule out clinically important effects. Given the clinical and statistical heterogeneity of the trials included in this comparison, no pooled estimate was derived across the studies (Comparison 01.01).

Pad changes over 24 hours

(Floratos 2002) used number of pad changes over 24 hours as the outcome measure, with no significant difference in the MD between treatment and control groups (Comparison 01.02).

Pad tests

Three studies (Joseph 2000; Moore 2006; Moore 1999) reported 24-hour pad test results and one (Floratos 2002) reported on a 1-hour pad test. Dubbelman 2004 and van Kampen 1998 also measured urine lost on the 24 hour pad test, but did not report standard deviations and therefore these data could not be included in the Table of Comparisons. Amongst the three studies included on the 24 hour pad test comparison, there were no significant differences between the groups at 3, 6 and 12 months (Comparison 01.03). On the 1-hour pad test reported by (Floratos 2002), results favoured the control group (Comparison 01.04). In the smaller trials (Moore 1999; Moore 2006; Floratos 2002) the standard deviations (SDs) were often larger than the means, suggesting highly skewed data. Although there was clinical heterogeneity, when data were combined there was no statistical heterogeneity (Comparisons 01.03 and 01.04).

2. Post-operative interventions using electric or magnetic energy (e.g. post-operative anal electrical stimulation, perineal electrical stimulation, transcutaneous electrical nerve stimulation (TENS), extracorporeal magnetic innervation (ExMI)) versus no treatment or sham treatment (Comparison 02)

Only a single trial with data was identified for this comparison (Moore 1999). This trial reported using PFMT with anal electrical stimulation. This was the second intervention group in the Moore trial.

One study of extracorporeal magnetic innervation versus no therapy or sham therapy (Nehra 2001) previously listed as ongoing was excluded as attempts to contact the authors for data were not successful.

Number not cured

There was no statistically significant difference between the groups in terms of reported UI symptoms (Comparison 02.01), but with wide CIs (RR 0.87; 95% CI 0.53 to 1.42).

Pad test

The data favoured the control group at 3 to 6 months, but there was no statistically significant difference between the groups on grams of urine lost (pad test) at any of the other time points (Comparison 02.02). SDs were large, indicating skewed distribution of data, and the confidence intervals were wide.

3. Post-operative lifestyle adjustment versus no treatment or sham treatment (Comparison 03)

No trials were identified.

4. Post-operative combinations of treatments versus no treatment or sham treatment (Comparison 04)

One trial reported using PFMT with anal electrical stimulation as well as biofeedback (Opsomer 1994). Incontinent men (loss of more than 1 gram of urine on pad test) at six weeks after RP were randomised to intervention and control groups. The intervention group had two sessions of biofeedback and electrical stimulation (type unspecified) in addition to continuing the PFMT taught to both groups. The data were few with cure rates based on only four men having UI at 3 to 6 months (Comparison 11.01). Pad test results were not reported in a form that could be used and attempts to contact the author were unsuccessful.

5. Post-operative use of one treatment versus another active treatment (Comparison 05)

Three trials comparing one active treatment to another were identified (Floratos 2002; Hoffman 2005; Moore 1999).

- Floratos 2002 randomised 28 men with post RP UI to PFMT and 14 to verbal feedback.
- Two trials (Hoffman 2005; Moore 1999) compared post-operative PFMT plus anal electrical stimulation with PFMT alone in men incontinent after RP. One trial (Moore 1999) reported two arms with a total of 37 men.
- Another arm of the (Hoffman 2005) study examined post-operative RP PFMT plus perineal electrical stimulation versus PFMT alone

One trial compared use of machine-led biofeedback to augment PFMT versus exercises taught using the standard method of verbal feedback from digital anal assessment (Joseph 2000). The verbal feedback group was treated as "control" or "PFMT alone" for the analysis. The trial was very small (a total of only 11 men) and reported as a pilot. One man had UI after TURP, the remainder after RP. Patients who were incontinent at least six months after surgery were randomised to either the biofeedback or verbal feedback groups. The results were not published, but the author supplied raw data on the pad test results so that means and standard deviations could be calculated by the review authors. Two men (of four still followed up) in the biofeedback group had urine loss on

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the pad test compared to none of three in the verbal group after three months. There are many potentially confounding variables in this trial, acknowledged by the author. Also, as all the men were incontinent for some time after surgery, they may represent a group with persistent UI.

One study of PFMT plus transcutaneous electrical nerve stimulation versus PFMT alone (Ceresoli 2002) previously listed as ongoing was excluded attempts to contact the author for data were not successful.

Number not cured

Again, definition of cure varied with each study: <1 gm urine loss on 1 hour pad test to <8 gm on 24 hour pad test. There was no difference in UI rates in the Moore 1999 trial, but confidence intervals were wide (Comparison 05.01).

Pad tests

Using a 20 minute provocative pad test, (Wille 2003) reported results favoured PFMT with anal ES at both 3 to 6 and 6 to12 months, but the 3 to 6 month MD was not significant and confidence intervals were wide. At 6 to 12 months the difference between groups was statistically significant with narrower confidence intervals (MD -3.31, 95% CI -0.67 to -0.55, Comparison 05.02) (Wille 2003). (Hoffman 2005) reported on a 1 hour provocative pad test. There were no significant differences between intervention and control groups (Comparison 05.03). In the (Moore 1999) trial, PFMT alone was favoured at the 3 to 6 month time period, but the distribution of pad test results was again very skewed, the CIs were wide and there was no significant difference at the other time points (Comparison 05.04).

Radical prostatectomy: prevention of UI in all men having surgery, intervention before and/or after prostatectomy

6. Pre with or without post-operative PFMT with or without biofeedback versus no treatment or sham therapy or verbal instruction (Comparison 06)

Five trials addressed this comparison (Bales 2000; Burgio 2005; Filocamo 2005; Mathewson-Chapman 97; Parekh 2003).

- Two trials (Bales 2000; Burgio 2005) compared preoperative PFMT plus biofeedback with a no-treatment or placebo-treatment control group for all men before RP.
- One trial (Filocamo 2005) compared postoperative PFMT plus digital anal biofeedback with a no-treatment or placebo-treatment control group for all men after RP.
- One small trial (Parekh 2003) attempted an intervention of both pre and post-operative PFMT plus biofeedback (digital or anal-probe) compared to no intervention in men undergoing RP.
- Another trial (Mathewson-Chapman 97) provided preoperative education and baseline perineal muscle evaluation to both treatment and control groups, with the treatment groups also receiving PFMT with biofeedback post-operatively.

In the (Bales 2000) trial, randomisation occurred preoperatively and initial instruction on PFMT and biofeedback training (surface electrodes) for the intervention group was provided two to four weeks prior to RP. The control group received only postoperative verbal instruction on PFMT, and both groups were encouraged to practice PFMT four times daily once the catheter was removed at two weeks after surgery. (Burgio 2005) randomised men to a single pre-operative session of biofeedback assisted PFMT and daily PFMT, or to a control group of usual care with simple instructions to interrupt the stream when voiding. In the (Filocamo 2005) trial, men received three formal PFMT instruction sessions from a therapist after operation. In the (Parekh 2003) trial, participants randomised to the intervention group were given two physical therapist led treatment sessions, which included PFMT and digital or anal-probe biofeedback, prior to surgery and every three weeks for 3 months post-operatively, as well as home exercises.

Number not cured

Data describing UI were reported for all four trials. Rates were derived for (Burgio 2005) as the data were originally reported by survival curve (time to continence). The definition of cure varied between the trials: one or fewer wet pads per day (Bales 2000; Filocamo 2005); no leakage on diary (Burgio 2005); self report (Mathewson-Chapman 97); and no pads or only one precautionary pad (Parekh 2003).

Only one large trial showed a significant benefit from PFMT plus biofeedback in prevention of incontinence (eg RR at 12 months, 0.11, 95% CI 0.05 to 0.26, Comparison 06.01.03) (Filocamo 2005). However, the remaining trials showed conflicting results, and the data could not be combined as there was statistically significant heterogeneity.

Pad changes and pad tests

In the two trials which reported these outcomes (Comparisons 06.02 and 06.03) there was no evidence to favour treatment in one small trial (Mathewson-Chapman 97) but less urine loss on a pad test in the other trial (Comparison 06.03, Filocamo 2005). However, the SDs were large and the confidence intervals were wide.

7. Pre with or without post-operative interventions using electric or magnetic energy (e.g. post-operative anal electrical stimulation, perineal electrical stimulation, transcutaneous electrical nerve stimulation (TENS),

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extracorporeal magnetic innervation (ExMI)) versus no treatment or sham treatment (Comparison 07)

No trials were identified.

8. Pre with or without post-operative lifestyle adjustment versus no treatment or sham treatment (Comparison 08)

No trials were identified.

9. Pre with or without post-operative combinations of treatments versus no treatment or sham treatment (Comparison 09)

No trials were identified.

10. Pre with or without post-operative use of one treatment versus another active treatment (Comparison 10)

One three-arm trial (Wille 2003) compared PFMT plus electrical stimulation with PFMT plus electrical stimulation plus anal probe biofeedback with PFMT alone.

Pad tests

Using a 20 minute provocative pad test, (Wille 2003) found that PFMT supplemented by anal electrostimulation with or without extra biofeedback resulted in less urine loss than PFMT alone at 6 months (Comparisons 10.01.03 and 10.02.03) but there was little difference between the groups with or without biofeedback (Comparison 10.03). However, the trial was small, the SDs large and the confidence intervals wide.

TURP: treatment of incontinent men, after surgery

11. Post-operative PFMT with or without biofeedback versus no treatment or sham therapy or verbal instruction (Comparison 11)

No trials were identified.

12. Post-operative interventions using electric or magnetic energy (e.g. post-operative anal electrical stimulation, perineal electrical stimulation, transcutaneous electrical nerve stimulation (TENS), extracorporeal magnetic innervation (ExMI)) versus no treatment or sham treatment (Comparison 12)

No trials were identified.

13. Post-operative lifestyle adjustment versus no treatment or sham treatment (Comparison 13)

No trials were identified.

14. Post-operative combinations of treatments versus no treatment or sham treatment (Comparison 14)

No trials were identified.

15. Post-operative use of one treatment versus another active treatment (Comparison 15)

No trials were identified.

TURP: prevention of UI in all men having surgery, intervention before and/or after prostatectomy

16. Pre with or without post-operative PFMT with or without biofeedback versus no treatment or sham therapy or verbal instruction (Comparison 16)

(Porru 2001) studied men after TURP for benign prostatic hyperplasia comparing PFMT with no treatment. The primary outcome was number remaining incontinent. The intervention was started on the first or second day postoperatively at the time of catheter removal, with the group taught to perform PFMT daily at home (varying frequency) with weekly digital anal reassessment and grading of pelvic muscle contraction by the therapist.

Pad tests (number not cured)

There were no significant differences between the groups in the rates of men incontinent at less than three months, but the confidence intervals were wide (Comparison 16.01).

17. Pre with or without post-operative interventions using electric or magnetic energy (e.g. post-operative anal electrical stimulation, perineal electrical stimulation, transcutaneous electrical nerve stimulation (TENS), extracorporeal magnetic innervation (ExMI)) versus no treatment or sham treatment (Comparison 17)

No trials were identified.

18. Pre with or without post-operative lifestyle adjustment versus no treatment or sham treatment (Comparison 18)

No trials were identified.

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19. Pre with or without post-operative combinations of treatments versus no treatment or sham treatment (Comparison 19)

No trials were identified.

20. Pre with or without post-operative use of one treatment versus another active treatment (Comparison 20)

No trials were identified.

Containment of UI (all men with residual UI)

21. External penile compression devices (penile clamps) versus no treatment or sham treatment (Comparison 21)

One trial compared three different penile compression devices (Cunningham clamp, U-Tex Male Adjustable Tension Band and C3 penile compression device) with a control period of no device (Moore 2004). A randomised block assignment was used with a multiple period crossover design, so that each of the 12 participants had a control period of no device and three periods in which the different devices were used. All external compression devices reduced the weight of urine lost on a four-hour pad test compared to the control period (P less than 0.05, Other Data Table 18.02), but none completely eliminated urine loss. Satisfaction was based on ease of application, comfort and efficacy. The device preferred by the largest number of men was also that with the lowest urine loss (the Cunningham clamp) (Other Data Table 21).
However, this was also the device with the greatest reduction in systolic blood flow velocity (P less than 0.05 versus control period, Other Data Table 21.03, 04), raising the possibility of safety issues if applied too tightly. In the trial, men were able to judge when to release the device, and the authors recommended that its use should therefore be limited to men who are cognitively intact, are aware of bladder filling, have normal genital sensation and intact penile skin, and have sufficient manual dexterity to open and close the device (Moore 2004).

Potential for publication bias

Potential for publication bias was examined graphically using a funnel plot. Using the dichotomous data from the same 12 trials included in the comparison for the sensitivity analysis, a funnel plot (relative risk, fixed effects) was generated in MetaView. Considerable funnel plot asymmetry was present, with the smaller trials favouring treatment missing from the left of the funnel, but those favouring control present. Since small studies usually tend to overestimate rather than underestimate the effect of an intervention (Sterne 2001), attributing the asymmetry to publication bias remains counterintuitive. Again, the more plausible explanation of funnel asymmetry lies in the poor quality of the studies or in true heterogeneity (variations in treatment type or intensity or risk differences attributable to studies of different sizes) (Higgins 2005). As there were only sixteen trials included in this review, no statistical analysis to examine publication bias was undertaken. In meta-analyses of less than 20 trials, sensitivity of these methods (rank correlation or linear regression) is considered low (Sterne 2001).

DISCUSSION

This review incorporates a broad array of possible interventions under the umbrella term of conservative management of post-prostatectomy UI. The populations studied included men undergoing prostatectomy for both benign and malignant disease. As well, the interventions occurred preoperatively, post operatively or both. Some early studies (e.g. Moore 1999; Joseph 2000) included men who had been incontinent for some time (up to months) after surgery. More recent studies have focused on the preoperative or post operative period immediately after catheter removal. Seventeen trials met the inclusion criteria, 15 trials amongst men after RP, one trial after TURP and one after either operation. There was considerable variation in the interventions, populations and outcome measures. Given this clinical heterogeneity it was decided to differentiate the studies, and the comparisons, by pre operative, post operative or combined intervention time periods and by type of surgery (TURP or RP) in this version of the review.

The majority of trials in this area continue to be of modest quality. Data were not available in all the trials for many of the pre-stated outcomes. Confidence intervals have tended to be wide except for the more recent studies, and it continues to be difficult to reliably identify or rule out a useful effect. All trials claimed to be randomised, and seven provided details of adequate concealment of randomisation (Burgio 2005; Filocamo 2005; Hoffman 2005; Moore 1999; Moore 2004; Moore 2006; van Kampen 1998). Blinding to intervention was not possible, and blinding of outcome assessment appeared to be absent in many trials as it was not discussed. Therefore, many of the included trials, especially the early ones, were vulnerable to allocation, intervention and measurement biases.

Attrition bias may have played a role in the results of some of the included trials and therefore affected the outcome of this review. One of the smaller trials (Franke 1998) lost half of the randomised participants by the end of the data collection period. Although most of those trials that lost participants provided an explanation of these losses, none accounted for the missing data in their analyses. The intention to treat principle mandates, at minimum, that patients stay in the group to which they are randomised (Juni 2001), which the included trials appeared to do. It is also suggested that primary outcomes for all patients randomised to groups should be recorded or estimated if not available. Three of

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the included trials (Filocamo 2005; Parekh 2003; Moore 2006) reported an analysis using the intention to treat principle, and one trial (Burgio 2005) used survivor analysis in the original study analysis. However, attrition bias is possible in a number of the other trials which do not discuss the issue.

Few trials used the primary outcomes of interest, patient reported symptoms and the standardized pad test. Most used a variety of subjective outcomes derived from patient reported symptoms to define continence. There were no trials which examined lifestyle adjustments in alleviating UI after prostatectomy.

There may be some enhancement of quality of life in men after prostatectomy through the support provided by attending a clinic offering these interventions (Moore 1999). (Hoffman 2005) also measured quality of life, and did not find a difference in this outcome between the 3 groups studied in rehabilitation programs, reporting that all groups improved on continence and quality of life, but that quality of life improvement was mostly achieved during the inpatient rehabilitation period which might also suggest some effect of being in a program. (Burgio 2005) also included a quality of life measure.

It is acknowledged that UI after prostatectomy will resolve over time in most men. There was some evidence from two trials that use of PFMT (compared to no treatment) may help to resolve this more quickly, based on the results from one trial amongst incontinent men (van Kampen 1998) and another which included all men immediately after catheter removal, thus not accounting for men who could have achieved continence spontaneously (Filocamo 2005). However, all the other comparable trials showed conflicting results, and the data could not be combined due to clinical and statistical heterogeneity. Two trials favouring treatment (Filocamo 2005; Wille 2003) enrolled men pre-operatively and started treatment post operatively without a baseline incontinence assessment. (Wille 2003) began treatment prior to catheter removal and included all men undergoing surgery, again not accounting for those with rapid recovery of continence post catheter removal.

The findings should continue to be treated with caution. The effectiveness of conservative measures in the longer term, or in those with persistent UI, remains inconclusive. Of interest in this update, (Filocamo 2005) reported significant improvement at longer term (6 to 12 months and after 12 months) and data from (Burgio 2005) favoured one session of pre-operative PFMT up to and including the 6 to12 month period. (Wille 2003) also reported a 12 month follow up. These three trials recruited preoperatively and included all men undergoing RP, not just those with persistent UI. It is likely that those with persistent UI are a different population.

However, one alternative intervention, a Cunningham clamp fitted to the shaft of the penis, proved satisfactory to 10 of 12 men with intractable UI (Moore 2004). This may be a viable alternative for some cognitively capable men providing they take into account safety issues such as adequate sensation and ability to remove the device when it feels too tight or the bladder is full. Men in one trial reported a preference for one type of external compression device compared to two others or no treatment. The effect of other conservative interventions such as lifestyle changes remains undetermined as no trials involving these interventions were identified.

Conservative interventions tend to be resource-intensive strategies that require people, equipment and clinic space, so administrators will look for evidence of efficacy. Funding has been an issue given the inconclusive nature of the evidence to date. For example, in the United States, the centres for both Medicare and Medicaid Services were considering whether to withdraw funding for biofeedback and pelvic floor electrical stimulation in the treatment of UI of any etiology based on a lack of evidence regarding effectiveness. Through a lobbying effort from service providers and manufacturers, these modalities continued to be covered in the United States (Thompson 2002). However, as controversy about funding is likely to continue, there is a need for continued research in the area to determine which groups of patients are most likely to benefit from conservative interventions.

AUTHORS' CONCLUSIONS

Implications for practice

In keeping with conclusions from earlier versions of this review, at this point there remains no clear support that conservative management of any type for postprostatectomy UI is either helpful or harmful, whether delivered as treatment to men who are incontinent or as prevention to all men undergoing surgery.

No trials have tested the effect of lifestyle changes alone. Long-term UI may be managed by external penile clamp, but there are safety problems.

Implications for research

UI after prostatectomy is a distressing problem and, although conclusive evidence does not exist, conservative approaches form part of current management. Well-designed clinical trials are needed to clarify the role of these therapies.

As there are known differences in the cause and prevalence of UI between men after TURP and after RP, these groups of men should continue to be studied separately. Prevention trials in all men having surgery should be evaluated separately from treatment trials of men with urinary incontinence after surgery.

Most of the trials included in this review used very different protocols of intervention type, timing and intensity. In order to determine the effects of specific protocols and modalities, large adequately powered trials using common protocols are needed. Replication studies using similar protocols in different populations

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would also assist in identifying the populations in which specific conservative management approaches are likely to be most effective.

Definitions and measurement of outcomes varied in the included trials. Future trials must attempt to use broadly accepted definitions, such as those of the International Continence Society and to make use of objective measures such as the pad test or urinary diaries in determining if continence has been achieved. Researchers must also focus on either the 1 hour or 24 hour pad test, as the results of these two measurements are not equivalent.

Lastly, authors should be encouraged to ensure appropriate randomisation and blinding of trials and to report these adequately, using the guidelines of the CONSORT statement.

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* *Indicates the major publication for the study*

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CHARACTERISTICS OF STUDIES

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

Bales 2000

Methods	Randomised: yes Method of allocation: not stated Blinding: Outcome assessment nurse not involved in intervention. Dropouts: None mentioned.
Participants	Recruitment: pre-operative Included: all men undergoing RP N=100 consecutive patients with stage T1c-T2c prostate cancer undergoing radical retropubic prostatectomy by a single surgeon randomised into 2 groups. Intervention N=50 Control N=50
Interventions	Pre-operative intervention. Intervention: 2-4 weeks prior to surgery, participants underwent a 45 minute session with nurse trained in biofeedback. Patients were instructed to perform graded PFMT. Contractions of 5-10 seconds, 10-15 repetitions were performed with biofeedback (surface electrodes used to measure muscle strength). Advised to practice the exercises 4 times per day until surgery Control: No biofeedback training. Written and brief verbal instructions from a nurse on how to perform PFMT (isolate muscle that stops urine flow, practice 4 times per day, 10-15 repetitions) Both: Encouraged to perform PME 4x per day after catheter removal 2 weeks post op Length of follow-up: 6 months
Outcomes	Main outcome: Time to return of continence measured by number of pads used Secondary outcomes: Quality of life measured by Hopkins Symptom Checklist (SCL-90-R) and Medical Outcomes Study Short Form Health Survey (SF-36) Continence definition: use of 1 pad or less per day Data collection: at 1, 2, 3, 4, and 6 months postoperatively
Notes	There was no significant difference in incontinence between the groups

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

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Burgio 2005

Methods	Randomised: yes Method of allocation: stratified by age and tumor differentiation, then randomised using computer generated random numbers, block size of 4 to ensure equity of number in each group. Blinding: Intervention providers and bladder diary scorers were blinded. Dropouts: 6 participants in the intervention group, and 7 in the control were excluded after randomisation as surgery was cancelled. At 6 months, 6 in the intervention and 4 in the control were lost to follow-up
Participants	Recruitment: pre-operative Included: all men undergoing RP N=125 volunteer patients randomised, 13 excluded after randomisation. Analysis on N=112 men aged 53-68 who underwent radical prostatectomy for prostate cancer. To be eligible, the men had to be ambulatory, continent and identied at least 1 week prior to their surgery. Intervention N=57 Control N=55
Interventions	Pre-operative intervention. Intervention: Single session of biofeedback (rectal probe to measure intra-abdominal rectal pressure and external anal sphincter contraction) assisted behavioural training. Feedback and verbal instruction used to teach control of pelvic muscles. Taught to contract sphincter during 2-10 seconds periods separated by 2-10 seconds of relaxation, dependent on ability. Written instructions for daily at home practice of 45 PFM exercises daily (3 sessions of 15 exercises each time). Additionally instructed to slow or interrupt voiding once daily. Encouraged to exercise daily preoperatively, then resume when catheter removed post-operatively Control: usual care of brief verbal instructions post operatively to interrupt the voiding stream plus any instruction from physician Length of follow-up: 6 months
Outcomes	Main outcome: Continual and/or episodic urine loss using bladder diaries, incontinent pads or other products Secondary outcomes: Impact of incontinence and quality of life pre-operatively and at follow-up contacts by IIQ, SCL-90-R and SF-36 Continence definition: 3 consecutive weekly 1 day diaries showing no leakage or a 7 day diary showing no leakage Data collection: One day bladder diaries mailed in each week. Questionaire on bladder control, lifestyle and 7 day bladder diary at 6 weeks, 3 months and 6 months post surgery
Notes	Time to continence was significantly reduced in the intervention group. The intervention group had a significantly smaller proportion of those with severe or continual leakage at 6 months, and stress type urine loss. No differences on quality of life, return to work or activities between the groups. Analysis by "intention to treat". Additional data supplied to KFH by author

Risk of bias

Item	**Authors' judgement**	**Description**
Allocation concealment?	Yes	A - Adequate

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Dubbelman 2004

Methods	Randomised: yes Method of allocation: not described. Blinding: not mentioned. Dropouts: 5 were excluded after consent (3 had positive nodes, 2 were not incontinent). Of the 70 men incontinent one week after catheter removal who were randomised to two groups, 7 dropped out due to bladder neck contracture (4), withdrawal of consent (2) or lack of understanding (1)
Participants	Recruitment: post-operative Included: men incontinent post RP, one week after catheter removal N=63 men completing the study, 31 in intervention group, 32 in control. All participants had a radial retropubic prostatectomy and lived within 75 km of hospital. Age range 61-67 years. Intervention N=31 Control N=32
Interventions	Post-operative intervention. Intervention: 9 or less sessions of physiotherapy guided pelvic floor exercises after surgery Control: Exercise instruction through information folder. Length of followup: 6.5 months
Outcomes	Main outcome: urinary incontinence on 1 hour and 24 hour pad tests Secondary outcome: Urodynamic study (urethral pressure profilometry Continence definition: Incontinence defined as loss of at least 1 gram of urine on 1-hour pad test or 4 grams on the 24 hour pad test Data collection: 1 and 26 weeks after catheter removal.
Notes	No significance difference in continence rates between the groups

Risk of bias

Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	B - Unclear

Filocamo 2005

Methods	Randomised: yes Method of allocation: Block randomisation, not further described. Blinding: not described Dropouts: At 12 months, 2 participants dropped out of the control group. Intention to treat:
Participants	Recruitment: post-operative Included: all men undergoing RRP N= 300 consecutive men post RRP, randomised after catheter removal to 2 groups. Intervention group: N= 150 Control group N=150

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Filocamo 2005 (*Continued*)

Interventions	Post-operative intervention. Intervention: Formal instruction (3 treatment sessions plus at home exercises) in PFMT using verbal explanation, palpation and visualization of the base of the penis with a mirror, in different positions and prior to sneezing, coughing or lifting. Biofeedback : contraction evaluated by digital anal control Control: No formal instruction. Length of follow-up: 12 months
Outcomes	Main outcome: urine loss on 1 hour and 24 hour pad tests plus number of pads used daily Continence definition: 0-1 pads per day Data collection: 1, 3, 6, and 12 months.
Notes	74% of the intervention group achieved continence at 3 months compared to only 30% of the control (a significant difference favoring intervention). Differences between the groups declined between 6-12 months, with most participants achieving continence in 1 year

Risk of bias

Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	D - Not used

Floratos 2002

Methods	Randomised: yes Method of allocation: randomized 2:1 to intervention: control groups. Blinding: Not mentioned Dropouts: 1 participant randomized to intervention unable to follow intervention protocol (unable to attend clinic. Provided with control invention. Intention to treat: yes
Participants	Recruitment: post-operative Included: men incontinent post RP one week after catheter removal N = 42 consecutive patients Intervention N=28 Control N=14
Interventions	Post-operative intervention. Intervention: Initiated after catheter removal. Intervention group received 15 treatment sessions (3 times per week for 30 minutes) of PFMT with EMG (surface) biofeedback in clinic Control: Instruction with verbal feedback and an information pamphlet with instructions to perform PME 50-100 times daily at home Length of follow-up: 6 months
Outcomes	Main outcome: incontinence episodes measured by 1 hour pad test and continence questionaire (pads used, number of incontinence episodes) Continence definition: Incontinence defined as a urine loss of > 1 gm on the 1 hour pad test. 2 or more pads/day a not deemed a "socially acceptable continence rate" Data collection: baseline, 1, 2, 3 and 6 months.

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Floratos 2002 (*Continued*)

Notes	Level of incontinence in both groups declined over the 6 months of the study. Control group had less urine loss and appeared to regain continence sooner, but the difference was not significant. Additional data supplied to KFH by author

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Franke 1998

Methods	Randomised: yes Method of allocation: not stated Blinding: none Dropouts: 2 with gravitational incontinence consistent with intrinsic sphincter deficiency Intention to treat: not clear.
Participants	Recruitment: post-operative Included: men incontinence post RP at 6 weeks post surgery N= 30 men 6 weeks post RP with post void residual of <50ml; no previous TURP, no urinary tract infection, no neurological conditions
Interventions	Post-operative intervention. Intervention: Biofeedback (perineal patch EMG) enhanced PFMT; exercise treatment sessions at 6, 7, 9, 11, and 16 weeks postoperatively Control: completed bladder diary but did not have any other intervention Length of follow-up: 12 months.
Outcomes	Main outcome: urine loss measured by voiding diary, 48 hour pad test (reported as mean grams of urine lost in 24 hours), and incontinence questionnaire Continence definition: Not clear. Participants described as "completely dry" or with "significant incontinence" Data collection: 6, 12 and 24 weeks
Notes	There were no significant differences between treatment or control groups on any of the outcome measures at any of the measurement intervals

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

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Hoffman 2005

Methods	Randomised: yes Method of allocation: computerized randomization. Blinding: unclear Dropouts: 1 participant from each intervention group had dropped out by discharge; 15 dropouts from the perineal group, 31 from the anal group and 5 from the control group dropped out by 3 months. Intention to treat: no
Participants	Recruitment: post-operative Included: men incontinent post RP in an inpatient rehabilitation program N= 180 men (prior to drop-outs) Randomly assigned to 3 groups (sixty in each group)
Interventions	Post-operative intervention. Intervention: (group 1): perineal E Stim plus physiotherapy (PFMT) Intervention (group 2): anal E Stim plus physiotherapy (PFMT) Control: PFMT alone. Length of follow-up: 3 months
Outcomes	Main outcome: urine loss measure on 1 hour pad test. Secondary outcomes: Quality of life (QLQ-C30) Continence definition: Self reports of incontinence. Data collection: admission and discharge from the rehabilitation program and at 3 months after discharge
Notes	All groups improved on continence and quality of life. Use of E stim was only of additional value in a compliant subgroup. Perineal E stim was better accepted than anal. Additional data supplied to KFH by author

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Joseph 2000

Methods	Randomisation: yes Method of allocation: Not described. Blinding: None. Dropouts: 3 did not return to clinic for all appointments, one had other health problems Intention to treat: No.
Participants	Recruitment: post-operative Included: men incontinent post RP or post TURP. UI of at least 6 months duration N= 11 patients at least 6 months post surgery (4 radical retropubic, 6 radical peritoneal, 1 TURP). Intervention N=6 Control N=5
Interventions	Post operative intervention. Intervention: Instruction in PFME including biofeedback with visual feedback as well as verbal to assist in identifying and discriminating muscles

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Joseph 2000 (*Continued*)

	Control: Instruction in PFME, squeezing of finger during digital rectal exam Both: weekly visit for a total of 4 clinic visits Length of follow-up: 12 months
Outcomes	Main outcome: urine loss measure by standardised pad test, , bladder diary, subjective estimation of degree of incontinence Secondary outcomes: Leak point pressure measured by video- urodynamics, Joseph Continence Assessment Tool Continence definition: subjective evaluation by participants Data collection: baseline, 3, 6, and 12 months.
Notes	No differences between the groups. Improvement seen in all patients at 12 months. Data not published in article. Raw data supplied to reviewer (KFH) who calculated means and standard deviations. These were reviewed by a second reviewer (KNM)

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Mathewson-Chapman 97

Methods	Randomised: yes, block procedure Method of allocation: unclear Blinding: none Dropouts: 2 - not accounted for. Intention to treat: not clear.
Participants	Recruitment: pre-operative Included: all men undergoing RP N= 53 men Randomised pre-operatively. Intervention N=27 Control N=24
Interventions	Pre and post-operative intervention. Intervention: Pre-operatively received further instruction and practice with PME protocol Home exercises and biofeedback (anal probe) (Incare 8900); practiced at home 3 times a week, starting with daily 15 PFMT and increasing by 10 every 4 weeks to a maximum of 35 PFMT Control: Post-operatively no further interventions until week 5 when pelvic muscle strength was assessed Both: Pre-operatively, both groups received 30 mintues prostate education programme and baseline 'perineal muscle evaluation' (not defined); as well all were taught to contract the perineal muscle and hold for a few seconds prior to standing, lifting or coughing and limit the amount of tea, chocolate, alcohol and over-the-counter medications Length of follow-up: 12 weeks.

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Mathewson-Chapman 97 (*Continued*)

Outcomes	Main outcome: urine loss measured by 24 hour pad test, frequency of micturitions (self-recorded bladder diary), number of pads used; days to achieve continence from baseline Secondary outcomes: Perineal muscle strength (method not described) Continence definition: self report of return of continence Data collection: Three day bladder diaries at weeks 2, 5, 9 and 12. 24hour pad test at weeks 5 and 12
Notes	Inclusion of other modalities such as caffeine limitation and using perineal muscles during any event which increased abdominal stress may have masked any treatment benefit

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Moore 1999

Methods	Randomised: yes Method of allocation: sealed envelopes. Blinding: physiotherapist blinded to results of control group. Dropouts: 5 Intention to treat: yes.
Participants	Recruitment: post-operative Included: men incontinent post RP. Median duration of UI 8 weeks post surgery, range 4-200 weeks N= 63 men (53 completed study) Randomised to 3 groups. Intervention N=18 and N=19 Control N=21
Interventions	Post-operative intervention. Intervention: Group 2: PFMT alone; Group 3: PFMT plus rectal electrical stimulation treated by one physiotherapist 30 minutes twice a week for 12 weeks. Intervention groups also did home exercises 3x/day gradually working up to 30 minutes per session lying, standing, sitting; strength, endurance, speed and control with maximum contractions of 5-10 seconds, 10-20 second relaxation and 12-20 repetitions; submaximum contractions at 65-75% of maximum strength with hold 20-30 seconds and equal rest time, 8-10 repetitions; speed was sets of quick repetitive contractions in a 10 second time span; control involved gradual recruitment to maximum contraction in 3 stages with 5 second hold at each stage and a slow release with rest 15-30 seconds Control: oral and written information about PFMT pre and post- operatively (standard treatment) Length of follow-up: 24 weeks.
Outcomes	Main outcome: urine loss measured by 24 hour pad test Secondary outcomes: quality of life measures (Incontinence Impact Questionnaire, European Organization for the research and treatment of Cancer-EORTC QLQ C-30, version 2), physical symptom inventory (adapted from Herr 1994)

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Moore 1999 (*Continued*)

	Continence definition: < or = 2 gm urine/ 24 hours Data collection: baseline, 12, 16 & 24 weeks after baseline.
Notes	Intervention perhaps administered too early - all subjects improved at the same rate; wide range of severity of urinary incontinence at study entry and size of SD of pad test results also may have resulted in Type II error

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Moore 2004

Methods	Randomised: yes (order of product testing: in 3s to treatment block of 4 periods (1 no device, 3 with devices) Block, multiple period crossover design using Latin square configuration; Method of allocation: sealed envelopes. Blinding: Research assistant not involved in study chose envelope; but research assistant and participants could not be blinded to intervention Dropouts: None Intention to treat: Not discussed.
Participants	Recruitment: post-operative Included: men incontinent post RP who required continuous pad protection for stress incontinence Inclusion criteria: normal perineal and penile sensation, intact penile skin, sufficient manual dexterity Exclusion criteria: overactive bladder, neurological disorders affecting sensation or circulation, cognitive impairment N = 12 men
Interventions	Post-operative intervention. Each participant had 4 periods (each lasted 1 day) 1. No device 2. C3 device 3. U-Tex device 4. Cunningham clamp.
Outcomes	Main outcome: 4 hour pad test. Secondary outcomes: resistive index , cavernosal flow Continence definition: Data collection:
Notes	None of the devices completely eliminated urine loss when applied at a comfortable pressure. Each device showed improvement in terms of urine lost, with Cunningham clamp having the lowest mean loss. Cunningham clamp significantly lowered flow, but ranked positively by participants. Unable to blind participants and research assistant to intervention Sample size calculation given and required size achieved.

Risk of bias

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Moore 2004 (*Continued*)

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Moore 2006

Methods	Randomised: yes Method of allocation: computer generated list of numbers; group allocation placed in sealed opaque envelopes; opened by subject after initial instruction session with therapist. Blinding: data entry by clerk blinded to group; therapist blinded to outcome of non-intervention group Dropouts: control = 7; treatment = 12
Participants	Recruitment: pre-operative Included: men incontinent post RP (> 8 grams urine lost on 24 hour pad test) at 4 weeks post surgery N =217 men from 3 centres with early stage prostate cancer Inclusion criteria: English speaking within 1 hour drive of research centre
Interventions	Post-operative intervention. Intervention: Maximum 24 weekly, 30-minute treatment protocol and home exercise protocol of 2-3 times a day Control: verbal and written information on PFME and weekly telephone contact by a urology nurse Both: At 4 weeks post surgery, both groups received standardized verbal and written instruction about PFMT and recovery after radical prostatectomy by one dedicated physiotherapist or registered nurse at each site Length of follow-up: 12 months
Outcomes	Main outcome: grams of urine loss on 24 hour pad test Secondary outcome: IPSS, IIQ-7 (Incontinence Impact Questionnaire), voiding diary, and subjective continence Continence definition: object was <8 gm of urine loss on 24 hour pad test; subjective continence defined as yes/no Data collection: All measures obtained at baseline (preoperatively) and at 4, 8, 12, 28 weeks and 1 year post operatively
Notes	At 8 weeks 21 (23%) control; 21 (20%) treatment were dry; at 12 weeks, 24 (28%) and 32 (32%); at 16 weeks, 33 (40%) and 42 (44%); at 28 weeks, 39 (50%) and 45 (47%); and at 12 months 73% of control and 67% of treatment groups were dry (<8 gm on pad test). No significant differences between groups on this or on symptom and quality of life measures or diary at any time point post operatively. The majority of subjects reported a low impact of incontinence as per the IIQ-7 and fewer LUTS at 12 months than at baseline as per the IPSS. The majority were very satisfied with treatment

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

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Opsomer 1994

Methods	Randomised: yes Method of allocation: method not described Blinding: none Drop outs: 4 Intention to treat: unclear.
Participants	Recruitment: post-operative Included: men incontinent post RP 6 weeks after six week after surgery N-=43 (39 completed study) Intervention N=21 Control N=22
Interventions	Post-operative intervention. Intervention: PFMT plus biofeedback plus electrical stimulation directed by physiotherapist Control: PFME on their own without medical supervision. Length of follow-up: 12 weeks.
Outcomes	Main outcome: urine loss measured by pad test. Continence definition: Data collection:
Notes	No statistical difference between groups as to recovery of continence. Abstract only - unable to contact author for further data

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Parekh 2003

Methods	Randomised: yes Method of allocation: Not described. Blinding: None Dropouts: 1 from each of the control and treatment groups. Reasons not described. Intention to treat: Yes, dropouts categorised as incontinent
Participants	Recruitment: pre-operative Included: all men scheduled for RP N= 38 patients with localized carcinoma of the prostate
Interventions	Pre and post-operative interventions. Intervention: 2 treatment sessions preoperatively. Session 1 consisted of PFMT in a hook lying position. Session 2 was on an exercise ball. Teaching methods varied and included verbal cues, visualization with an anatomical model, palpation or biofeedback with rectal probe. Post-operatively, PFMT was reviewed and participants were seen every 3 weeks for 3 months by a physiotherapist. Home exercise for 6 months or more for those requiring further physical therapy guidance

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Parekh 2003 (*Continued*)

	Control: No formal education on PFMT pre-operatively, telephone or face to face follow-up at least monthly Length of follow-up: 12 months
Outcomes	Main outcome: urine loss measured by number of pads used daily Continence definition: 0 pads or 1 precautionary pad used Data collection: UI questionnaires at 6, 12, 16, 20, 28, and 52 weeks
Notes	Greater number of the intervention group gained continence earlier than the control group at 3 months (only point of statistical difference). Minimal long term effect as continence rates the same at 1 year

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Porru 2001

Methods	Randomised: yes Method of allocation: Not described. Blinding: Report stated that urologist performing digital evaluation of pelvic floor muscle contraction was blinded to the study group. Dropouts: Intervention - 2, control - 1. Reason reported was non-attendance at all clinic appointments. Intention to treat: None.
Participants	Recruitment: pre-operative Included: all men undergoing TURP N=58 men (55 completed study) with benign prostatic hypertrophy randomized to 2 groups. Intervention N=30 Control N=28
Interventions	Pre and post-operative intervention. Intervention: Initial visit before surgery, digital evaluation of pelvic muscle contraction strength. Verbal instruction, feedback and reinforcement on contraction was given to teach selective contraction of anal sphincter and relaxation of abdominal muscles. Verbal and written instruction given for home PFMT. Instructed to practice contractions 45 times per day (3 groups of 15 contractions) Control: Not specified. Both: Voiding diaries initated after catheter removal. Length of follow-up: 4 weeks
Outcomes	Main outcome: Urine loss (incontinence episodes) measured by 48 hour bladder diaries completed weekly Secondary outcomes: Muscle contraction strength by digital evaluation Scale 0-4 [0=none, 4=strong]. Pressure flow: Urine flowmetry pre-operatively and 1 month post-operatively. Symptoms: AUA (American Urological Association) symptom score preoperatively and 30 days after surgery. Quality of life: ICS male questionnaire. Data collection: at catheter removal and weekly for 4 weeks.

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Porru 2001 (*Continued*)

Notes	Significant increase in muscle strength in intervention group by week 4. Both groups showed improvement in symptom score and quality of life post-operatively, no significant difference between groups. Significantly better satisfaction with life in intervention group compared to control at 4 weeks. Significant difference in voiding intervals between the groups at weeks 2 and 3, but not week 4. No difference in uroflowmetry. Significantly less incontinence in the intervention group at weeks 1, 2, and 3. No difference at week 4. Concluded that PFMT quickens the return to normal voiding post TURP

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

van Kampen 1998

Methods	Randomised: yes Method of allocation: stratified randomisation with sealed envelopes. Sratified by gms of urine loss (<50 , >50, <250, >250 gm) Binding: yes Dropouts:5. Intention to treat: yes Outcome assessor not involved with the study.
Participants	Recruitment: post-operative Included: men incontinent post RP 15 days after surgery after catheter removal N=102 eligible, 98 completed. Intervention N=50 Control N=52
Interventions	Post-operative intervention. Intervention: 1 session of PFMT in hospital before discharge and then saw the physiotherapist for 1-2 weeks for as long as UI persisted. 90 daily home exercises sitting, standing and lying. 7 men unable to contract PFM or with weak contraction received electrical stimulation by anal probe Control: No formal PFMT instruction but saw the therapist at 1-2 weeks and received placebo stimulation and information about aetiology of UI Both: received bladder training to increase bladder capacity Length of follow-up: 12 months
Outcomes	Main outcome: Urine loss measured by 24 and 1 hour pad tests. 24 hour pad test done daily until continence achieved. 1 hour pad test when loss of < 2 grams of urine to confirm continence Secondary outcomes: Subjective UI by visual analogue scale Fluid Volume Chart Quality of Life - questionnaire designed for study. Continence definition:

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van Kampen 1998 (*Continued*)

	Numbers cured defined as <2gm urine loss on 24 and 1 hour pad tests Data collection: Subject assessment of continence preoperatively (during screening), and at 1, 6 and 12 months. Daily weighing of pads by participants (24 hour pad test)
Notes	Pragmatic study; policy of management left to clinical judgment as to which protocols to add to PFMT regime. 63 of the eligible subjects were unable to participate because of geographical reasons; demographics and post- operative variables did not differ from the 102 subjects who were in the treatment groups

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Wille 2003

Methods	Randomised: yes Method of allocation: Not described Blinding: Not mentioned Dropouts: Numbers participating at 3 and 12 months identified (for pad test, N= 116 at baseline, 79 at 3 months and 124 at 12 months), reason for dropouts not described
Participants	Recruitment: pre-operative Included: all men undergoing RP N= 139 randomized (number in each group at various data collection points varied) Intervention N=46 and N=46 Control N=47
Interventions	Post-operative intervention. Intervention Group 1: PFMT + ES. PFMT as above plus instructed by dedicated in ES via surface anal electrode and bioimpulser (biphasic pulse with 1 second bursts, 5 second pulse width, 2 second pulse trains Intervention group 2: PFMT + ES + biofeedback. As above plus biofeedback (anal probe) 15 minutes twice daily for 3 months Control: PFMT alone. All: PFMT by physiotherpist, 20-30 minute sessions for 3 days, instructed to perform exercises twice daily for 3 months plus3 week rehabilitation program after discharge. Regular interaction with health professional for 6 weeks after surgery, encouraged to performed treatment for 3 months post surgery Length of follow-up: 12 months
Outcomes	Main outcome: urine loss measure by continence questionaire and 20 minute provocative pad test Continence definition: Reported use of 0-1 pads on questionaire (subjective) or loss of less than 1 gram of urine on pad test Data collection: baseline (after catheter removal), 3 months and 12 months post operatively

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Wille 2003 (*Continued*)

Notes	No significant differences in continence rates between the three groups at baseline, 3 months or 12 months. (objective)	
Risk of bias		
Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	B - Unclear

gm(s)=gram(s); PFMT=pelvic floor muscle training; TURP=transurethral resection of the prostaste; UI=urinary incontinence;

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

Study	Reason for exclusion
Bennett 1997	Abstract only, no data included. Attempts to contact the author for data unsuccessful
Bocker 2002	Data from study that included male postprostatectomy and female post-polio patients. Translation obtained as reported in German. Data from the two groups were not separated and therefore not in a usable form
Ceresoli 2002	Attempts to contact the author for data unsuccessful.
Chang 1998	Data from study which involved post TURP patients. Two groups, treatment and control. Not randomly assigned to groups, first 25 consecutively assigned to control, next 25 to intervention
Cornel 2005	Descriptive study. No control group.
Crevenna 2003	Descriptive pilot study. No control group.
Griebling 1999	Data reported in paper presentation and in later published report did not contain sufficient detail of analysis to include in tables of comparison. Attempts to contact authors not successful in providing further data
Ip 2004	Education ntervention (refrigerator magnet) not an intervention included in review
McGlynn 2004	Descriptive study of change in education delivery approach. No control group.
Nehra 2001	Abstract only. Attempts to contact authors for further data unsuccessful
Pulker 2002	Descriptive study. No control group.

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(*Continued*)

Salinas Casado 1991	Descriptive study. No control group. Article in Spanish with English abstract.
Salinas Casado 1996	Descriptive study. No control group. Article in Spanish with English abstract.
Seki 2005	Descriptive study. No control group.
Yokoyama 2004	Data not in usable format for inclusion in tables of comparison. Lead author contacted, but no further data other than that published was available
Zermann 1999	Descriptive study. No control group.

TURP=transurethral resection of the prostate

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

Glazener 2004

Trial name or title	Conservative treatment for urinary incontinence in men after prostate surgery (MAPS)
Methods	
Participants	Men after radical prostatectomy (RP)and endoscopic resection of prostate (ERP)
Interventions	Plevic floor muscle training and bladder training
Outcomes	Urinary incontinence, faecal incontinence, sexual function, quality of life, economic outcomes
Starting date	December 2004
Contact information	Glazener CMA c.glazener@abdn.ac.uk
Notes	Duration of trial 4.5 years

ExMI=extracorporeal magnetic innervation

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DATA AND ANALYSES

Comparison 1. Treatment after RP: Post-operative PMFT +/- Biofeedback vs no treatment /sham treatment

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Number not cured (worse, unchanged or improved)	6		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
1.1 less than 3 months	4		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.2 within 3-6 months	5		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.3 within 6-12 months	3		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.4 after 12 months	0		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
2 Pad changes over 24 hours	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
2.1 less than 3 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
2.2 within 3-6 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
2.3 within 6-12 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
2.4 after first year	0		Mean Difference (IV, Fixed, 95% CI)	Not estimable
3 24 hour pad test (grams of urine lost)	3		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
3.1 less than 3 months	3	225	Mean Difference (IV, Fixed, 95% CI)	24.92 [-20.77, 70.61]
3.2 within 3-6 months	3	210	Mean Difference (IV, Fixed, 95% CI)	9.33 [-25.01, 43.68]
3.3 within 6-12 months	3	217	Mean Difference (IV, Fixed, 95% CI)	29.43 [-7.37, 66.23]
3.4 after first year	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
4 1 hour pad test (grams of urine lost)	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
4.1 less than 3 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
4.2 within 3-6 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
4.3 within 6-12 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
4.4 after first year	0		Mean Difference (IV, Fixed, 95% CI)	Not estimable

Comparison 2. Treatment after RP: Interventions using electrical or magnetic energy vs no treatment / sham treatment

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 No. not cured (worse, unchanged or improved): PFMT + anal Estim vs no treatment	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
1.1 less than 3 months	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.2 within 3-6 months	0		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.3 within 6-12 months	0		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.4 after 12 months	0		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable

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2 24 hour pad test (grams of urine lost): PFMT + anal Estim vs no treatment	1	Mean Difference (IV, Fixed, 95% CI)	Totals not selected
2.1 less than 3 months	1	Mean Difference (IV, Fixed, 95% CI)	Not estimable
2.2 within 3-6 months	1	Mean Difference (IV, Fixed, 95% CI)	Not estimable
2.3 within 6-12 months	1	Mean Difference (IV, Fixed, 95% CI)	Not estimable
2.4 after first year	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable

Comparison 4. Treatment after RP: Combinations of treatments vs no treatment/ sham treatment

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 No. not cured (worse, unchanged, improved): PFMT + anal Estim + Biofeedback vs no treatment	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
1.1 less than 3 months	0		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.2 within 3-6 months	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.3 within 6-12 months	0		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.4 after 12 months	0		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable

Comparison 5. Treatment after RP: One treatment vs another treatment

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 No. not cured (worse, unchanged or improved): PFMT + anal EStim vs PFMT	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
1.1 less than 3 months	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.2 within 3-6 months	0		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.3 within 6-12 months	0		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.4 after 12 months	0		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
3 1 hour pad test (grams of urine lost): PFMT + anal Estim vs PFMT	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
3.1 less than 3 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
3.2 within 3-6 months	0		Mean Difference (IV, Fixed, 95% CI)	Not estimable
4 24 hour pad test (grams of urine lost): PFMT + anal Estim vs PFMT	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
4.1 less than 3 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
4.2 within 3-6 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
4.3 within 6-12 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
4.4 after first year	0		Mean Difference (IV, Fixed, 95% CI)	Not estimable

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5 1 hour pad test (grams of urine lost): PFMT + perineal Estim vs PFMT	1	Mean Difference (IV, Fixed, 95% CI)	Totals not selected
5.1 less than 3 months	1	Mean Difference (IV, Fixed, 95% CI)	Not estimable
5.2 within 3-6 months	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable

Comparison 6. Prevention of UI before +/- after RP: Pre-operative RP PFMT+/- Biofeedback vs no treatment /sham treatment

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 No. not cured (worse, unchanged or improved)	5		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
1.1 less than 3 months	5		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.2 within 3-6 months	5		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.3 within 6-12 months	4		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.4 after 12 months	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
2 Pad changes over 24 hours	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
2.1 less than 3 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
2.2 3-6 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
3 24 hour pad test	2		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
3.1 less than 3 months	2	351	Mean Difference (IV, Fixed, 95% CI)	-10.18 [-19.11, -1.24]
3.2 within 3-6 months	1	300	Mean Difference (IV, Fixed, 95% CI)	-19.00 [-24.22, -13.78]
3.3 within 6-12 months	1	300	Mean Difference (IV, Fixed, 95% CI)	-14.4 [-18.27, -10.53]
3.4 after first year	1	298	Mean Difference (IV, Fixed, 95% CI)	-1.0 [-1.81, -0.19]

Comparison 10. Prevention of UI before +/- after RP: One treatment vs another active treatment

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 20 minute pad test (grams of urine lost): PFMT + anal Estim vs PFMT	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
1.2 within 3-6 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
1.3 within 6-12 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
2 20 minute pad test (grams of urine lost): PFMT + anal Estim + Biofeedback vs PFMT	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
2.1 less than 3 months	0		Mean Difference (IV, Fixed, 95% CI)	Not estimable
2.2 within 3-6 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
2.3 within 6-12 months	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable

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3 20 minute pad test (grams of urine lost): PFMT + anal Estim vs PFMT + anal Estim + biofeedback	1	Mean Difference (IV, Fixed, 95% CI)	Totals not selected
3.2 within 3-6 months	1	Mean Difference (IV, Fixed, 95% CI)	Not estimable
3.3 within 6-12 months	1	Mean Difference (IV, Fixed, 95% CI)	Not estimable

Comparison 16. Prevention of UI before +/- after TURP: Pre-operative PFMT+/- Biofeedback vs no treatment / sham/ verbal

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Number not cured (worse, unchanged or improved)	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
1.1 less than 3 months	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.2 within 3-6 months	0		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.3 within 6-12 months	0		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable

Comparison 21. Containment: Post-operative external penile compression devices (penile clamps) vs no treatment/sham treatment

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Number of men satisfied with device			Other data	No numeric data
2 Mean urine loss (grams of urine on pad test)			Other data	No numeric data
3 Penile Doppler blood flow (mean systolic velocity)			Other data	No numeric data
4 Penile Doppler blood flow (mean resistence to flow index)			Other data	No numeric data

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Analysis 1.1. Comparison 1 Treatment after RP: Post-operative PMFT +/- Biofeedback vs no treatment /sham treatment, Outcome 1 Number not cured (worse, unchanged or improved).

Review: Conservative management for postprostatectomy urinary incontinence

Comparison: 1 Treatment after RP: Post-operative PMFT +/- Biofeedback vs no treatment /sham treatment

Outcome: 1 Number not cured (worse, unchanged or improved)

Study or subgroup	PFMT n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
1 less than 3 months				
Franke 1998	6/13	3/10		1.54 [0.50, 4.69]
Moore 1999	12/18	14/21		1.00 [0.64, 1.56]
Moore 2006	61/93	58/92		1.04 [0.84, 1.29]
van Kampen 1998	5/48	23/52		0.24 [0.10, 0.57]
2 within 3-6 months				
Dubbelman 2004	21/31	23/32		0.94 [0.68, 1.31]
Franke 1998	1/7	1/8		1.14 [0.09, 15.08]
Moore 1999	8/18	7/21		1.33 [0.60, 2.95]
Moore 2006	42/87	39/78		0.97 [0.71, 1.32]
van Kampen 1998	2/48	12/52		0.18 [0.04, 0.77]
3 within 6-12 months				
Floratos 2002	4/28	0/14		4.66 [0.27, 80.84]
Moore 2006	31/93	22/84		1.27 [0.80, 2.02]
van Kampen 1998	2/48	9/49		0.23 [0.05, 1.00]
4 after 12 months				

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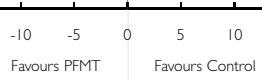
Analysis 1.2. Comparison 1 Treatment after RP: Post-operative PMFT +/- Biofeedback vs no treatment /sham treatment, Outcome 2 Pad changes over 24 hours.

Review: Conservative management for postprostatectomy urinary incontinence

Comparison: 1 Treatment after RP: Post-operative PMFT +/- Biofeedback vs no treatment /sham treatment

Outcome: 2 Pad changes over 24 hours

Study or subgroup	PFMT N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 less than 3 months						
Floratos 2002	28	1.2 (1.1)	14	0.9 (1)		0.30 [-0.36, 0.96]
2 within 3-6 months						
Floratos 2002	28	0.8 (1)	14	0.4 (0.5)		0.40 [-0.05, 0.85]
3 within 6-12 months						
Floratos 2002	28	0.4 (0.7)	14	0.2 (0.4)		0.20 [-0.13, 0.53]
4 after first year						



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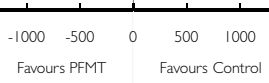
Analysis 1.3. Comparison 1 Treatment after RP: Post-operative PMFT +/- Biofeedback vs no treatment /sham treatment, Outcome 3 24 hour pad test (grams of urine lost).

Review: Conservative management for postprostatectomy urinary incontinence

Comparison: 1 Treatment after RP: Post-operative PMFT +/- Biofeedback vs no treatment /sham treatment

Outcome: 3 24 hour pad test (grams of urine lost)

Study or subgroup	PFMT N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 less than 3 months						
Joseph 2000	6	58.67 (97.9)	5	30.5 (40.41)		28.17 [-57.80, 114.14]
Moore 1999	18	87 (123)	21	104 (176)		-17.00 [-111.31, 77.31]
Moore 2006	93	114.8 (299.8)	82	71.4 (114.2)		43.40 [-22.35, 109.15]
Subtotal (95% CI)	**117**		**108**			**24.92 [-20.77, 70.61]**
Heterogeneity: Chi² = 1.07, df = 2 (P = 0.59); I² =0.0%						
Test for overall effect: Z = 1.07 (P = 0.29)						
2 within 3-6 months						
Joseph 2000	5	4.4 (6.26)	5	0 (0)		0.0 [0.0, 0.0]
Moore 1999	18	74 (131)	21	67 (137)		7.00 [-77.24, 91.24]
Moore 2006	87	44.7 (141.7)	74	34.9 (100.9)		9.80 [-27.82, 47.42]
Subtotal (95% CI)	**110**		**100**			**9.33 [-25.01, 43.68]**
Heterogeneity: Chi² = 0.00, df = 1 (P = 0.95); I² =0.0%						
Test for overall effect: Z = 0.53 (P = 0.59)						
3 within 6-12 months						
Joseph 2000	4	6.25 (9.46)	3	0 (0)		0.0 [0.0, 0.0]
Moore 1999	17	70 (114)	16	54 (103)		16.00 [-58.05, 90.05]
Moore 2006	93	40.42 (208.46)	84	6.59 (8.26)		33.83 [-8.57, 76.23]
Subtotal (95% CI)	**114**		**103**			**29.43 [-7.37, 66.23]**
Heterogeneity: Chi² = 0.17, df = 1 (P = 0.68); I² =0.0%						
Test for overall effect: Z = 1.57 (P = 0.12)						
4 after first year						
Subtotal (95% CI)	**0**		**0**			**0.0 [0.0, 0.0]**
Heterogeneity: not applicable						
Test for overall effect: not applicable						
Test for subgroup differences: Chi² = 0.67, df = 2 (P = 0.72), I² =0.0%						



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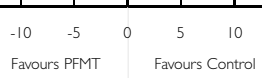
Analysis 1.4. Comparison 1 Treatment after RP: Post-operative PMFT +/- Biofeedback vs no treatment /sham treatment, Outcome 4 1 hour pad test (grams of urine lost).

Review: Conservative management for postprostatectomy urinary incontinence

Comparison: 1 Treatment after RP: Post-operative PMFT +/- Biofeedback vs no treatment /sham treatment

Outcome: 4 1 hour pad test (grams of urine lost)

Study or subgroup	PFMT N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 less than 3 months						
Floratos 2002	28	6.5 (11.4)	14	3 (4.1)		3.50 [-1.24, 8.24]
2 within 3-6 months						
Floratos 2002	28	3.7 (9.9)	14	1.3 (2.4)		2.40 [-1.48, 6.28]
3 within 6-12 months						
Floratos 2002	28	3.1 (8.1)	14	0 (0)		0.0 [0.0, 0.0]
4 after first year						



Analysis 2.1. Comparison 2 Treatment after RP: Interventions using electrical or magnetic energy vs no treatment / sham treatment, Outcome 1 No. not cured (worse, unchanged or improved): PFMT + anal Estim vs no treatment.

Review: Conservative management for postprostatectomy urinary incontinence

Comparison: 2 Treatment after RP: Interventions using electrical or magnetic energy vs no treatment / sham treatment

Outcome: 1 No. not cured (worse, unchanged or improved): PFMT + anal Estim vs no treatment

Study or subgroup	PFMT + anal Estim n/N	No treatment n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
1 less than 3 months				
Moore 1999	11/19	14/21		0.87 [0.53, 1.42]
2 within 3-6 months				
3 within 6-12 months				
4 after 12 months				

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Analysis 2.2. Comparison 2 Treatment after RP: Interventions using electrical or magnetic energy vs no treatment / sham treatment, Outcome 2 24 hour pad test (grams of urine lost): PFMT + anal Estim vs no treatment.

Review: Conservative management for postprostatectomy urinary incontinence

Comparison: 2 Treatment after RP: Interventions using electrical or magnetic energy vs no treatment / sham treatment

Outcome: 2 24 hour pad test (grams of urine lost): PFMT + anal Estim vs no treatment

Study or subgroup	PFMT + anal Estim N	Mean(SD)	No treatment N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 less than 3 months						
Moore 1999	19	156 (168)	21	104 (176)		52.00 [-54.64, 158.64]
2 within 3-6 months						
Moore 1999	19	202 (242)	21	67 (137)		135.00 [11.41, 258.59]
3 within 6-12 months						
Moore 1999	19	98 (132)	21	54 (103)		44.00 [-29.92, 117.92]
4 after first year						

Analysis 4.1. Comparison 4 Treatment after RP: Combinations of treatments vs no treatment/ sham treatment, Outcome 1 No. not cured (worse, unchanged, improved): PFMT + anal Estim + Biofeedback vs no treatment.

Review: Conservative management for postprostatectomy urinary incontinence

Comparison: 4 Treatment after RP: Combinations of treatments vs no treatment/ sham treatment

Outcome: 1 No. not cured (worse, unchanged, improved): PFMT + anal Estim + Biofeedback vs no treatment

Study or subgroup	PFMT + aEstim + BFB n/N	No treatment n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
1 less than 3 months				
2 within 3-6 months				
Opsomer 1994	3/20	1/19		2.85 [0.32, 25.07]
3 within 6-12 months				
4 after 12 months				

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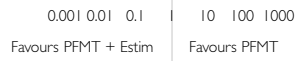
Analysis 5.1. Comparison 5 Treatment after RP: One treatment vs another treatment, Outcome 1 No. not cured (worse, unchanged or improved): PFMT + anal EStim vs PFMT.

Review: Conservative management for postprostatectomy urinary incontinence

Comparison: 5 Treatment after RP: One treatment vs another treatment

Outcome: 1 No. not cured (worse, unchanged or improved): PFMT + anal EStim vs PFMT

Study or subgroup	PFMT + anal e stim n/N	PFMT n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
1 less than 3 months				
Moore 1999	11/19	12/18		0.87 [0.52, 1.44]
2 within 3-6 months				
3 within 6-12 months				
4 after 12 months				



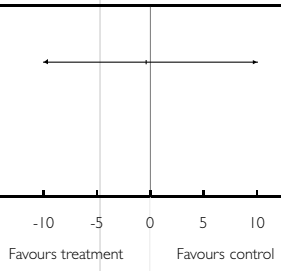
Analysis 5.3. Comparison 5 Treatment after RP: One treatment vs another treatment, Outcome 3 1 hour pad test (grams of urine lost): PFMT + anal Estim vs PFMT.

Review: Conservative management for postprostatectomy urinary incontinence

Comparison: 5 Treatment after RP: One treatment vs another treatment

Outcome: 3 1 hour pad test (grams of urine lost): PFMT + anal Estim vs PFMT

Study or subgroup	PFMT+ anal Estim N	Mean(SD)	PFMT N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 less than 3 months						
Hoffman 2005	59	89.6 (89.5)	60	90 (111.8)		-0.40 [-36.76, 35.96]
2 within 3-6 months						



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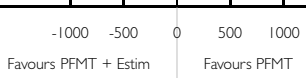
Analysis 5.4. Comparison 5 Treatment after RP: One treatment vs another treatment, Outcome 4 24 hour pad test (grams of urine lost): PFMT + anal Estim vs PFMT.

Review: Conservative management for postprostatectomy urinary incontinence

Comparison: 5 Treatment after RP: One treatment vs another treatment

Outcome: 4 24 hour pad test (grams of urine lost): PFMT + anal Estim vs PFMT

Study or subgroup	PFMT + anal e stim N	Mean(SD)	PFMT N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 less than 3 months						
Moore 1999	19	156 (168)	18	87 (123)		69.00 [-25.53, 163.53]
2 within 3-6 months						
Moore 1999	19	202 (242)	18	74 (131)		128.00 [3.49, 252.51]
3 within 6-12 months						
Moore 1999	19	98 (132)	17	70 (114)		28.00 [-52.37, 108.37]
4 after first year						



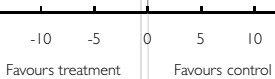
Analysis 5.5. Comparison 5 Treatment after RP: One treatment vs another treatment, Outcome 5 1 hour pad test (grams of urine lost): PFMT + perineal Estim vs PFMT.

Review: Conservative management for postprostatectomy urinary incontinence

Comparison: 5 Treatment after RP: One treatment vs another treatment

Outcome: 5 1 hour pad test (grams of urine lost): PFMT + perineal Estim vs PFMT

Study or subgroup	PFMT + peri Estim N	Mean(SD)	PFMT alone N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 less than 3 months						
Hoffman 2005	59	85.3 (100.6)	60	90 (111.8)		-4.70 [-42.90, 33.50]
2 within 3-6 months						



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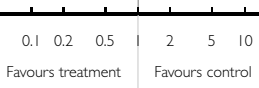
Analysis 6.1. Comparison 6 Prevention of UI before +/- after RP: Pre-operative RP PFMT+/- Biofeedback vs no treatment /sham treatment, Outcome 1 No. not cured (worse, unchanged or improved).

Review: Conservative management for postprostatectomy urinary incontinence

Comparison: 6 Prevention of UI before +/- after RP: Pre-operative RP PFMT+/- Biofeedback vs no treatment /sham treatment

Outcome: 1 No. not cured (worse, unchanged or improved)

Study or subgroup	PFMT + biofeedback n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
1 less than 3 months				
Bales 2000	38/47	38/50		1.06 [0.86, 1.31]
Burgio 2005	49/54	51/53		0.94 [0.85, 1.04]
Filocamo 2005	121/150	138/150		0.88 [0.80, 0.96]
Mathewson-Chapman 97	8/27	10/24		0.71 [0.34, 1.50]
Parekh 2003	6/19	12/19		0.50 [0.24, 1.05]
2 within 3-6 months				
Bales 2000	20/47	19/50		1.12 [0.69, 1.82]
Burgio 2005	32/53	40/51		0.77 [0.59, 1.00]
Filocamo 2005	39/150	105/150		0.37 [0.28, 0.50]
Mathewson-Chapman 97	1/27	0/24		2.68 [0.11, 62.81]
Parekh 2003	4/19	7/19		0.57 [0.20, 1.63]
3 within 6-12 months				
Bales 2000	3/47	2/50		1.60 [0.28, 9.13]
Burgio 2005	22/51	30/50		0.72 [0.49, 1.06]
Filocamo 2005	6/150	53/150		0.11 [0.05, 0.26]
Parekh 2003	3/19	4/19		0.75 [0.19, 2.91]
4 after 12 months				
Filocamo 2005	2/150	18/148		0.11 [0.03, 0.46]



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Analysis 6.2. Comparison 6 Prevention of UI before +/- after RP: Pre-operative RP PFMT+/- Biofeedback vs no treatment /sham treatment, Outcome 2 Pad changes over 24 hours.

Review: Conservative management for postprostatectomy urinary incontinence

Comparison: 6 Prevention of UI before +/- after RP: Pre-operative RP PFMT+/- Biofeedback vs no treatment /sham treatment

Outcome: 2 Pad changes over 24 hours

Study or subgroup	Treatment N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 less than 3 months						
Mathewson-Chapman 97	27	1.1 (2.1)	24	2.04 (2.7)		-0.94 [-2.28, 0.40]
2 3-6 months						
Mathewson-Chapman 97	27	0.6 (1.6)	24	1.8 (2.7)		-1.20 [-2.44, 0.04]

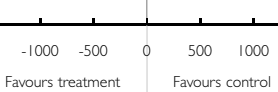
Analysis 6.3. Comparison 6 Prevention of UI before +/- after RP: Pre-operative RP PFMT+/- Biofeedback vs no treatment /sham treatment, Outcome 3 24 hour pad test.

Review: Conservative management for postprostatectomy urinary incontinence

Comparison: 6 Prevention of UI before +/- after RP: Pre-operative RP PFMT+/- Biofeedback vs no treatment /sham treatment

Outcome: 3 24 hour pad test

Study or subgroup	Treatment N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
1 less than 3 months							
Filocamo 2005	150	53.6 (41)	150	63.8 (38.1)		99.5 %	-10.20 [-19.16, -1.24]
Mathewson-Chapman 97	27	120.4 (249.2)	24	126 (215.6)		0.5 %	-5.60 [-133.18, 121.98]
Subtotal (95% CI)	**177**		**174**			**100.0 %**	**-10.18 [-19.11, -1.24]**
Heterogeneity: Chi² = 0.00, df = 1 (P = 0.94); I² =0.0%							
Test for overall effect: Z = 2.23 (P = 0.026)							
2 within 3-6 months							
Filocamo 2005	150	13.2 (13.9)	150	32.2 (29.5)		100.0 %	-19.00 [-24.22, -13.78]
Subtotal (95% CI)	**150**		**150**			**100.0 %**	**-19.00 [-24.22, -13.78]**
Heterogeneity: not applicable							



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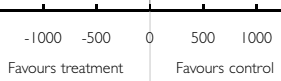
Study or subgroup	Treatment N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Test for overall effect: Z = 7.14 (P < 0.00001)							
3 within 6-12 months							
Filocamo 2005	150	3.4 (4.8)	150	17.8 (23.7)		100.0 %	-14.40 [-18.27, -10.53]
Subtotal (95% CI)	**150**		**150**			**100.0 %**	**-14.40 [-18.27, -10.53]**
Heterogeneity: not applicable							
Test for overall effect: Z = 7.29 (P < 0.00001)							
4 after first year							
Filocamo 2005	150	1.4 (2.3)	148	2.4 (4.5)		100.0 %	-1.00 [-1.81, -0.19]
Subtotal (95% CI)	**150**		**148**			**100.0 %**	**-1.00 [-1.81, -0.19]**
Heterogeneity: not applicable							
Test for overall effect: Z = 2.41 (P = 0.016)							
Test for subgroup differences: Chi^2 = 89.23, df = 3 (P = 0.00), I^2 =97%							



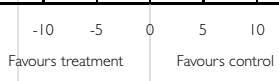
Analysis 10.1. Comparison 10 Prevention of UI before +/- after RP: One treatment vs another active treatment, Outcome 1 20 minute pad test (grams of urine lost): PFMT + anal Estim vs PFMT.

Review: Conservative management for postprostatectomy urinary incontinence

Comparison: 10 Prevention of UI before +/- after RP: One treatment vs another active treatment

Outcome: 1 20 minute pad test (grams of urine lost): PFMT + anal Estim vs PFMT

Study or subgroup	PFMT + anal E stim N	Mean(SD)	PFMT N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
2 within 3-6 months						
Wille 2003	26	4.7 (10)	27	9.74 (22.1)		-5.04 [-14.22, 4.14]
3 within 6-12 months						
Wille 2003	39	0.39 (0.5)	41	3.7 (9)		-3.31 [-6.07, -0.55]



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Analysis 10.2. Comparison 10 Prevention of UI before +/- after RP: One treatment vs another active treatment, Outcome 2 20 minute pad test (grams of urine lost): PFMT + anal Estim + Biofeedback vs PFMT.

Review: Conservative management for postprostatectomy urinary incontinence

Comparison: 10 Prevention of UI before +/- after RP: One treatment vs another active treatment

Outcome: 2 20 minute pad test (grams of urine lost): PFMT + anal Estim + Biofeedback vs PFMT

Study or subgroup	PFMT + analEstim+BFB		PFMT		Mean Difference	Mean Difference
	N	Mean(SD)	N	Mean(SD)	IV,Fixed,95% CI	IV,Fixed,95% CI
1 less than 3 months						
2 within 3-6 months						
Wille 2003	26	4.45 (12.4)	27	9.74 (22.1)		-5.29 [-14.89, 4.31]
3 within 6-12 months						
Wille 2003	44	0.43 (0.66)	41	3.7 (9)		-3.27 [-6.03, -0.51]

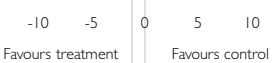
Analysis 10.3. Comparison 10 Prevention of UI before +/- after RP: One treatment vs another active treatment, Outcome 3 20 minute pad test (grams of urine lost): PFMT + anal Estim vs PFMT + anal Estim + biofeedback.

Review: Conservative management for postprostatectomy urinary incontinence

Comparison: 10 Prevention of UI before +/- after RP: One treatment vs another active treatment

Outcome: 3 20 minute pad test (grams of urine lost): PFMT + anal Estim vs PFMT + anal Estim + biofeedback

Study or subgroup	PFMT + anal Estim		PFMT + Estim + BFB		Mean Difference	Mean Difference
	N	Mean(SD)	N	Mean(SD)	IV,Fixed,95% CI	IV,Fixed,95% CI
2 within 3-6 months						
Wille 2003	26	4.7 (10)	26	4.45 (12.4)		0.25 [-5.87, 6.37]
3 within 6-12 months						
Wille 2003	39	0.39 (0.5)	44	0.43 (0.66)		-0.04 [-0.29, 0.21]



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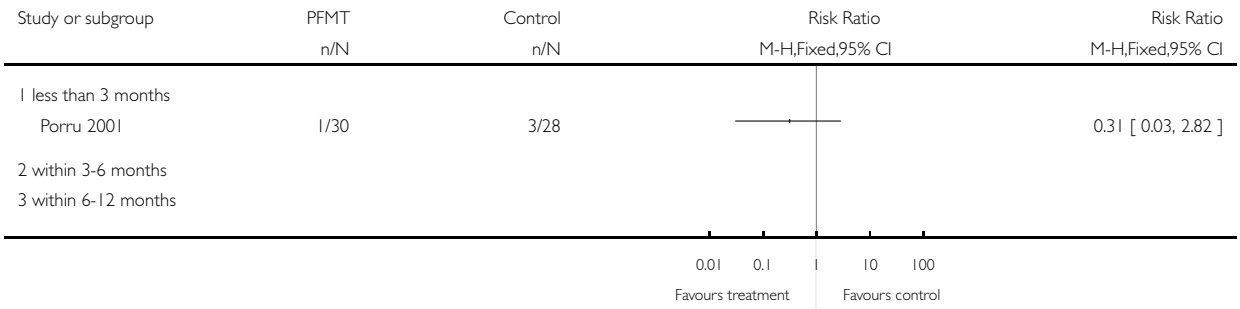
Analysis 16.1. Comparison 16 Prevention of UI before +/- after TURP: Pre-operative PFMT+/- Biofeedback vs no treatment / sham/ verbal, Outcome 1 Number not cured (worse, unchanged or improved).

Review: Conservative management for postprostatectomy urinary incontinence

Comparison: 16 Prevention of UI before +/- after TURP: Pre-operative PFMT+/- Biofeedback vs no treatment / sham/ verbal

Outcome: 1 Number not cured (worse, unchanged or improved)



Analysis 21.1. Comparison 21 Containment: Post-operative external penile compression devices (penile clamps) vs no treatment/sham treatment, Outcome 1 Number of men satisfied with device.

Number of men satisfied with device

Study	Control (no device)	U-Tex	C3	Cunningham
Moore 2004	0/12	0/12	2/12	10/12

Analysis 21.2. Comparison 21 Containment: Post-operative external penile compression devices (penile clamps) vs no treatment/sham treatment, Outcome 2 Mean urine loss (grams of urine on pad test).

Mean urine loss (grams of urine on pad test)

Study	Control (no device)	U-Tex	C3	Cunningham
Moore 2004	122.8 gm (SD 130.8)	53.3 gm (SD 65.7) P<0.05 vs Control (no device)	32.3 gm (SD 24.3) P<0.05 vs Control (no device)	17.1 gm (SD 21.3) P<0.05 vs Control (no device)

Analysis 21.3. Comparison 21 Containment: Post-operative external penile compression devices (penile clamps) vs no treatment/sham treatment, Outcome 3 Penile Doppler blood flow (mean systolic velocity).

Penile Doppler blood flow (mean systolic velocity)

Study	Control (no device)	U-Tex	C3	Cunningham
Moore 2004	N=12 men R: 12.4 (SD 2.8) L: 12.3 (SD 3.0)	N=12 men R: 11.9 (SD 4.4) L: 13.8 (SD 7.3)	N=12 men R: 12.4 (SD 5.5) L: 11.7 (SD 4.7)	N=12 men R: 9.5 (SD 2.3) L: 7.3 (SD 3.0)

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Penile Doppler blood flow (mean systolic velocity) (*Continued*)

				P<0.05 vs Control (no device)

Analysis 21.4. Comparison 21 Containment: Post-operative external penile compression devices (penile clamps) vs no treatment/sham treatment, Outcome 4 Penile Doppler blood flow (mean resistence to flow index).

Penile Doppler blood flow (mean resistence to flow index)

Study	**Control (no device)**	**U-Tex**	**C3**	**Cunningham**
Moore 2004	N=12 men R: 0.9 (SD 0.1) L: 0.87 (SD 0.1)	N=12 men R: 0.93 (SD 0.08) L: 0.91 (SD 0.11)	N=12 men R: 0.92 (SD 0.1) L: 0.92 (SD 0.11)	N=12 men R: 0.92 (SD 0.13) L: 0.86 (SD 0.29)

WHAT'S NEW

Last assessed as up-to-date: 20 February 2007.

Date	Event	Description
16 September 2008	Amended	Converted to new review format.

HISTORY

Protocol first published: Issue 3, 1998

Review first published: Issue 4, 1999

Date	Event	Description
21 February 2007	New citation required and conclusions have changed	Substantive amendment. In this update (Issue 2 2007) , seven trials have been added to the review. The total number of studies now included is 17. In this update, comparisons were separated on the basis of type of surgery and as well whether the intervention occurred pre- or post-operatively
25 February 2004	New citation required and conclusions have changed	Substantive update Issue 2 2004. In this update, five trials have been added to the review. One trial previously listed as included was excluded after attempts to contact the author to access data were unsuccessful. The total

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(*Continued*)

		number of studies now included is 10
23 January 2001	New citation required and conclusions have changed	Substantive update Issue 2 2001

CONTRIBUTIONS OF AUTHORS

For the updates in 2004 and 2006, the original lead review author (KNM) and an additional review author (KFH) independently undertook the quality assessment, data extraction and collation. KFH took the lead in updating the text and completed the data entry, which were then checked and commented upon by the other review authors.

For the earlier versions, two of the original review authors undertook the quality assessment of the trials and the data extraction independently. This information was then collated and checked by the original lead review author (KNM) for agreement and in the few instances where this did not occur, consensus was reached after checking with the other review authors. For the 2004 and 2006 updates, KFH updated the text and entered the data. These were checked by the other review authors, whose additional comments and edits were then incorporated.

DECLARATIONS OF INTEREST

One of the reviewers (KNM) was an investigator in three of the seventeen included trials. Another (CMAG) is the Chief Investigator of an ongoing study (Glazener 2004).

SOURCES OF SUPPORT

Internal sources

- University of Alberta , Edmonton, Alberta, Canada.

External sources

- National Health Service Research and Development Programme, UK.
- Chief Scientist Office, Scottish Executive Health Department, UK.

INDEX TERMS

Medical Subject Headings (MeSH)

Biofeedback, Psychology; Exercise Therapy; Prostatectomy [*adverse effects]; Randomized Controlled Trials as Topic; Urinary Incontinence [etiology; *therapy]

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MeSH check words

Humans; Male

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