

## LITERATURE REVIEW

# Pelvic floor muscle training for the management of urinary incontinence following radical prostatectomy

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### Abstract

Urinary incontinence (UI) after a radical prostatectomy (RP) is a common but devastating condition that can have a significant negative impact on quality of life (QoL). This article reviews the current literature on pelvic floor muscle training (PFMT) for the management of UI following a RP. A comprehensive literature search was carried out that identified 14 randomized controlled trials (RCTs) and seven systematic reviews. It is difficult to draw definitive conclusions from the RCTs because of their heterogeneous methodology, particularly the diverse regimes of pelvic floor exercises that were prescribed. At present, there appears to be weak to moderate evidence for the use of PFMT for UI after RP. Spontaneous recovery from symptoms undoubtedly occurs in the first year after surgery, irrespective of management; however, the current evidence demonstrates that recovery time can be shortened with specific interventions. It is essential that further good-quality RCTs are carried out, specifically trials including QoL outcome measures.

*Keywords:* pelvic floor muscle training, radical prostatectomy, urinary incontinence.

### Introduction

The effectiveness of pelvic floor muscle training (PFMT) for the treatment of urinary incontinence (UI) in women, including both stress UI (SUI) and mixed UI, has been well documented by several good-quality randomized controlled trials (RCTs) and systematic reviews (Bø 2004). However, the benefits of conservative treatment for male UI have not been investigated as rigorously because research has been biased towards female subjects (Dorey 1998; Wilson *et al.* 2005). The present paper evaluates and critically appraises the current literature on PFMT for the management of UI following radical prostatectomy (RP), and includes reflection on clinical practice.

### Prevalence

A report by the Office for National Statistics (Westlake & Cooper 2008) stated that 35 000 new cases of prostate cancer were diagnosed in the UK in 2004 alone. This accounted for 24% of all male cancers. The above authors also reported that the incidence of prostate cancer increased by 41% from 67 to 95 per 100 000 males during the period between 1993–1995 and 2002–2004. The mortality rate fell by 12% in the same interval.

The prevalence of lifelong UI following RP can vary greatly, and may be dependent upon the definition of incontinence, methods of data collection used, including outcome measures, and the follow-up period (Moul 1998). A literature review by Palmer (2000) looked at six prevalence studies and found that the rate of UI one-year post-surgery ranged between 2% and 35%.

### Clinical presentation

Post-RP UI may be caused by damage of the neurovascular bundles surrounding the prostate

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**Table 1.** Search strategy: (PEDro) Physiotherapy Evidence Database; (AMED) Allied and Complementary Medicine Database; (CINAHL) Cumulative Index to Nursing and Allied Health Literature; (MEDLINE) Medical Literature Analysis and Retrieval System Online; (EMBASE) Excerpta Medica Database; (MSN) Microsoft Network; (DH) Department of Health; (NHS) National Health Service; (SIGN) Scottish Intercollegiate Guidelines Network; and National Institute for Health and Clinical Excellence (NICE)

Variable	Details
Keywords:	
population	Prostatectomy, radical prostatectomy, prostate, prostate surgery, prostate cancer, post-prostatectomy, urinary incontinence, incontinence, urinary leakage, urinary symptoms
intervention	Pelvic floor exercises, pelvic floor, physiotherapy, physical therapy, exercise, therapy, treatment, conservative treatment, management, conservative management, intervention, electrical stimulation, stimulation, biofeedback
comparison	Not applicable
outcome measures	Quality of Life Scale, Visual Analogue Scale, Disability Rating Index
Limits	Humans, English language
Databases	PEDro, AMED, Cochrane Library, CINAHL, MEDLINE, EMBASE
Search engines	Google, Yahoo, MSN
Websites	DH, NHS Information Centre, Centre for Evidence Based Medicine, SIGN, NICE
Hand searches	All reference lists in papers were hand-searched for relevant articles
Expert opinion	Interactive CSP website, peers, University of Bradford teacher

or scarring/damage to the urethral sphincter (Dornan 2005). Men may present post-operatively with SUI, urge UI (UII), urgency, daytime frequency, nocturia, post-micturition dribble or any combination of these problems (Dorey 2001).

#### Literature search

A comprehensive and systematic literature search was carried out using the population, intervention, comparison and outcomes model (Philadelphia Panel 2001) to obtain a list of relevant keywords to enter into pertinent databases. It was decided to include papers from the past 10 years because the purpose of the present review was to evaluate the current evidence. Two comprehensive systematic reviews of the subject did not identify any good-quality studies prior to 1997 (Wilson *et al.* 2005; Hunter *et al.* 2007). The search strategy is detailed in Table 1.

The present review includes articles on PFMT with or without biofeedback, electrical stimulation (ES), and extracorporeal magnetic innervation (ExMI) for the treatment of UI in men who have undergone RP for prostate cancer. Systematic reviews of the treatment of male UI are also included in the analysis.

Papers on erectile dysfunction, post-micturition dribble and faecal incontinence were excluded. Studies exclusively investigating symptoms/treatments after transurethral resec-

tion of the prostate and non-randomized trials were also excluded.

The material identified by the literature search consisted of 14 RCTs and seven systematic reviews, which included a Cochrane Review (Hunter *et al.* 2007) and the Third International Consultation on Incontinence (Wilson *et al.* 2005).

#### Critical appraisal

The Scottish Intercollegiate Guidelines Network (SIGN) grading system (SIGN 2004a) was used to critically appraise the papers. This modified hierarchy of evidence is based on the design and methodology of studies. The grading system uses tables of key questions/checklists about aspects of the research that are known to have a bearing on the validity of the results and conclusions of each type of study (Table 2). The RCTs and systematic reviews discussed in the present paper are summarized in Tables 3 and 4, respectively.

#### Evidence

The evidence from RCTs found in the present review of the literature was separated into three categories, each covering similar treatment strategies, to allow for comparison between studies. Systematic reviews and guidelines are also discussed.

**Table 2.** Scottish Intercollegiate Guidelines Network grading system (SIGN 2004a): (RCTs) randomized controlled trials

Grade	Level of evidence
1++	High-quality meta-analyses, systematic reviews of RCTs or RCTs with a very low risk of bias
1+	Well-conducted meta-analyses, systematic reviews or RCTs with a low risk of bias
1-	Meta-analyses, systematic reviews or RCTs with a high risk of bias
2++	High-quality systematic reviews of case control or cohort studies; high-quality case control or cohort studies with a very low risk of confounding, bias or chance, and a high probability that the relationship is causal
2+	Well-conducted case control or cohort studies with a low risk of confounding, bias or chance, and a moderate probability that the relationship is causal
2-	Case control or cohort studies with a high risk of confounding, bias or chance, and a significant risk that the relationship is not causal
3	Non-analytic studies (e.g. case reports and case series)
4	Expert opinion

### Literature review

#### *Post-operative pelvic floor muscle training with or without biofeedback versus control group*

Ten RCTs were identified in this category. Five trials found a positive results for PFMT, but five trials found no benefit when comparing PFMT including biofeedback and/or ES with a control group. The five trials that found a positive relationship were those by Van Kampen *et al.* (2000), Parekh *et al.* (2003), Filocamo *et al.* (2005), Burgio *et al.* (2006) and Manassero *et al.* (2007).

A large block RCT of 300 consecutive patients compared formal post-operative therapy sessions and home exercises with a control group who received no formal instruction (Filocamo *et al.* 2005). At 3 months, 74% of the intervention group had regained continence compared with 30% of the control group ( $P < 0.00001$ ). However, there was no statistical difference between groups at one year, by which time 97.7% of the intervention group and 88% of the control group had achieved continence. Continence was defined by the use of one or no containment pads. Filocamo *et al.* (2005) concluded that early PFMT after RP could significantly reduce the time taken to regain continence. Appropriate statistical tests were used on the data, but limitations to the above study included a lack of outcome measure data and no indication of whether there was any assessor blinding.

A double-blind RCT of 102 men complaining of UI after RP concluded that PFMT significantly improved continence outcomes in comparison to control treatment with placebo electrotherapy (Van Kampen *et al.* 2000). The intervention group also received biofeedback and some had additional ES. The weekly placebo electrotherapy consisted of a false interferential current given via surface electrodes on the

thighs and abdomen. The intervention group showed significantly reduced duration ( $P = 0.0001$ ) and degree ( $P = 0.0010$ ) of incontinence compared with the control group. The primary outcome measures were 1- and 24-h pad tests. Both the treatment and control groups in the above study were taught bladder training, which might have had some influence on the results. However, Van Kampen *et al.* (2000) did suggest that it might have been efficacious to carry out urodynamics on all subjects in order to gain a better insight into the type of incontinence that they suffered. For the purposes of the study, it could have been more constructive to exclude any form of bladder training.

A prospective RCT of 107 men with UI post RP compared subjects who were taught post-operative PFMT by two urologists with a control group who received no advice or treatment (Manassero *et al.* 2007). This study excluded men with a weak or absent PFM contraction and patients with symptoms of detrusor instability. Manassero *et al.* (2007) found a statistically significant difference in continence status in favour of the treatment group at 1 ( $P = 0.04$ ), 3 ( $P = 0.03$ ), 6 ( $P = 0.01$ ) and 12 months ( $P < 0.01$ ) after surgery. The outcome measures used were the 24-h pad test, the Visual Analogue Scale (VAS) and quality of life (QoL) scores. Mean urinary leakage was significantly higher in the treatment group at baseline. This could have been avoided if the stratification had been done prior to randomization rather than afterwards. Further limitations of the above study were that 13 patients were lost to follow-up (all from the control group) and only one QoL question was used. The exclusion of men with weak or absent contraction could suggest that the results may not be valid for the general population of men following RP.

**Table 3.** Characteristics of the randomized controlled trials (RCTs) included in the literature review: (RP) radical prostatectomy; (TURP) transurethral resection of the prostate; (PFMT) pelvic floor muscle training; (QoL) quality of life; (OAB) overactive bladder; (ICS-male) International Continence Society Male Continence Questionnaire; (UI) urinary incontinence; (EMG) electromyography; (DRE) digital rectal examination; (PFMEs) pelvic floor muscle exercises; (VAS) Visual Analogue Scale; (IPSS) International Prostate Symptom Score; (ES) electrical stimulation; (EORTC QLQ-C30) European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire – Core 30; (IIQ-7) Incontinence Impact Questionnaire; (ExMI) extracorporeal magnetic innervation; (IIRS) Intrusiveness Rating Scale; and (BF) biofeedback

Reference (level of evidence; SIGN 2004)	Recruitment	Inclusion criteria	Exclusion criteria	Randomization	Intervention	Comparison	Outcome measures	Main findings	Conclusion	Limitations
Bales <i>et al.</i> (2000) (1 –)	Pre-operative consecutive recruitment of 100 US men scheduled to undergo RP by one surgeon	Stage T1c–T2c prostate cancer	Previous TURP, pre-existing neurological disease	No details given	Forty-five-minute BF session (surface electrodes) with nurse 2–4 weeks prior to RP and PFMT four times a day	Control: written and brief verbal instructions about PFMT	Number of pads used daily; interviews at 1, 2, 3, 4 and 6 months post-surgery	At 6 months, 94% of the BF group and 96% of the control group were continent (no significant difference, $P=0.596$ )	Pre-operative BF training did not improve continence outcomes in men undergoing RP	No power calculations done; poor outcome measure; no real control group; only one BF session given
Burgio <i>et al.</i> (2006) (1 +)	Pre-operative recruitment of 125 US men via seven urology clinics/practices between January 1996 and January 2001	Ambulatory, continent, identified at least one week prior to surgery	More than two episodes of UI in past 6 months, documented incontinence in bladder diary, impaired mental status, less than one week to surgery	Stratified (age and Gleason score), computer-generated random numbers (block size of 4), intervention givers blinded	One session of BF-assisted behavioural training (rectal pressure measured via balloons) and advice on daily PFMT (15 squeezes, maximum 10-s hold, three times a day), advised midstream stop	Usual care: verbal instruction post-operatively to practice mid-stream stop	Bladder diary one day per week; pad usage; 7-day bladder diary; QoL scores at 6 weeks, 3 months and 6 months post-operatively	Intent to treat analysis; 70% compliance in study group at 6 months; the study group showed a significant improvement in severe/continual leakage at 6 months ( $P=0.04$ ); less pads used ( $P<0.05$ ), and less leakage on coughing ( $P=0.003$ ) and sneezing ( $P=0.02$ ); no differences in QoL scores, return to work or activities	Pre-operative behavioral training can quicken recovery of continence and decrease severity of urine leakage following RP	Pad usage as outcome measure; difficult to ascertain the benefit of BF training as an adjunct to PFMT because no comparison was done with PFMT alone

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**Table 3.** *Continued*

Reference (level of evidence; SIGN 2004)	Recruitment	Inclusion criteria	Exclusion criteria	Randomization	Intervention	Comparison	Outcome measures	Main findings	Conclusion	Limitations
Filocamo <i>et al.</i> (2005) (1 –)	Post-operative consecutive recruitment of 300 Italian men scheduled for RP between 2000 and 2004	Stage T1 or T2 prostate cancer	Prior bladder or prostate surgery, prior UI or faecal incontinence, neurogenic dysfunction of lower urinary tract, pre-operative history of OAB	Block randomization (no other details given)	Three formal sessions using palpation, verbal instruction and DRE; home PFMT, including 'the Knack'	Control: no formal instructions given	Pad tests (1- and 24-h); pad usage; bladder diary; ICS- male measured at 1, 3, 6 and 12 months; continence=0 or 1 pad per day	Some 74% of the PFMT group achieved continence compared with 30% of controls at 3 months (statistically significant); no difference between the groups at one year	Early PFMT after RP reduces continence recovery time; therapy should start as soon as possible after surgery	No details of Oxford Scale grades given; no outcome measure data presented; no details of who gave sessions; no details of blinding
Floratos <i>et al.</i> , 2002 (2 –)	Post-operative consecutive recruitment of 42 men with UI following RP (one week post-operatively) for localized prostate cancer; four surgeons; multi-centre trial (no other details given)	Urinary incontinence, ability to participate in study, good general health, willingness to participate	Significant peri-operative complication pre-operative UI, previous pelvic or lower urinary tract surgery, psychiatric illness	Weighted randomization (2:1) – exercise group: controls	Fifteen formal sessions of BF (three times a week) of 30 min duration, surface EMG and home PFMT (50–100 times a day)	Control: verbal PFMT and DRE; written information given to contract pelvic floor muscles 80–100 times a day	One-hour pad test and continence questions (number pads used and number of episodes of leakage) measured at 1, 2, 3 and 6 months	Level of incontinence declined in both groups, control group had less urine loss (not statistically significant); total objective continence rate at 7 months was 90%	Intensive verbal instruction and BF effective as early management of post-operative UI; no additional benefit of formal sessions control group; small sample	Home exercise instruction differed between groups, no baseline data provided, data only supplied in qualitative percentages; lack of real control group; small sample

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Table 3. Continued

Reference (level of evidence; SIGN 2004)	Recruitment	Inclusion criteria	Exclusion criteria	Randomization	Intervention	Comparison	Outcome measures	Main findings	Conclusion	Limitations
Franke <i>et al.</i> (2000) (2 -)	Post-operative consecutive recruitment of 30 US men undergoing RP between July 1996 and July 1997	Willingness to participate	Previous TURP, neurological condition that affects lower urinary tract, post-void residual >60 mL, urinary tract infection	Authors indicate randomization used, but no details given	Forty-five-minute BF sessions (surface EMG) at 6, 7, 9, 11 and 16 weeks post-operatively, 20 repetitions of PFMT three times a day, timed voiding and lifestyle advice given	Control (no information)	Forty-eight-hour pad test and voiding diary 6, 12 and 24 weeks post-operatively	No significant difference found between groups in number of pads used or number of incontinence episodes; observed trend in favour of control group; overall, 87% pad-free at 6 months	Treatment programme of early BF-enhanced PFMT did not significantly affect continence when compared with controls	Small sample, commencing therapy 6 weeks post-operatively may not be regarded as 'early' treatment, lack of baseline data given, no details about stage of cancer, digital rectal examination not performed
Manassero <i>et al.</i> (2007) (1 +)	Pre-operative consecutive recruitment of 107 Italian men undergoing bladder-neck-sparing RP from May 2003 to January 2005	Able to comply with protocol, able to regularly attend clinics, confirmed UI (>2 g loss on 24-h pad test), good general health	History of pre-operative UI, peri-operative problems, active rectal lesions or infection, psychiatric or neurological disorders, inability to contract or weak PFMs, detrusor instability	Computer-generated random numbers, stratified	Active PFMEs, 15 squeezes three times a day increasing to 90 per day; supine, sitting, standing and functional positions treatment given by two urologists	Assessment only	VAS, 24-h pad test and QoL at 1, 3, 6 and 12 months post-operatively	Difference between men remaining incontinent between groups significant at one ( $P=0.04$ ), 3 ( $P=0.03$ ), 6 ( $P=0.01$ ) and 12 months ( $P<0.01$ )	Early intensive PFMT can increase the number of continent patients in the first year; authors recommend that PFMT should be offered to all patients	Only one QoL question (taken from the IPSS) used; mean urinary leakage was significantly higher in the men in the treatment group at baseline; men with weak or absent PFMs excluded, which means results may not be valid on the general population of men following RP; 13 lost to follow-up (all in control group)

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Table 3. Continued

Reference (level of evidence; SIGN 2004)	Recruitment	Inclusion criteria	Exclusion criteria	Randomization	Intervention	Comparison	Outcome measures	Main findings	Conclusion	Limitations
Mathewson-Chapman (1997) (1 -)	Pre-operative consecutive recruitment of 53 US men scheduled for RP for localized disease; two surgeons	None	None	Block randomization	PFMT with BF three times a week for 12 weeks; started during week 3 (removal of catheter)	Control: no treatment; baseline muscle assessment pre-operatively and again at 5 weeks	Twenty-four-hour pad test, number of pads used, number of incontinence episodes, bladder diary, pad tests at weeks 5 and 12, diaries at 2, 5, 9 and 12 weeks	Intervention group regained continence at a mean of 51 days and controls at 56 days; no statistically significant difference between groups	Men can experience leakage for 1-80+ days post RP; BF enhances learning and performance of PFMT	Both groups given instruction in 'the Knack' and lifestyle advice; not clear how often the intervention group received BF; dropout data missing; raw data not published
Moore et al. (1999) (1 -)	Post-operative consecutive recruitment of 63 Canadian men undergoing RP from December 1995 to February 1997	Four or more weeks after operation, UI (>2 g urine loss on pad test), neurologically normal, within a 2-h drive of study centre	Unable to speak and/or read English, pacemaker, previous ES, active rectal lesions or infection, known bladder	Computer-generated randomization with sealed envelopes; therapist blinded to results of control group	Group A: information (as controls) plus physiotherapy twice a week (30-min sessions) for 12 weeks (strength, endurance and functional training) Group B: as above, but also surface ES	Control: written information and brief verbally taught PFMT	Twenty-four-hour pad test, number of incontinence episodes, number and volume of voids, number of pads used, EORTC QLQ-C30, IIQ-7	No statistically significant difference between groups in treatment outcome, rapid improvement in continence seen in all groups from baseline to 12 weeks (no improvement in QoL scores), no difference in age groups in terms of total urine loss at 12 or 24 weeks	Rapid improvement in all groups may have masked any treatment benefits, no evidence to support the idea that either PFMT and/or ES enhances recovery	Fifty-four per cent of sample had pre-operative lower urinary tract symptoms, intervention may have been given too early, validity testing for one QoL measure done on a female population

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Table 3. Continued

Reference (level of evidence; SIGN 2004)	Inclusion criteria	Exclusion criteria	Randomization	Intervention	Comparison	Outcome measures	Main findings	Conclusion	Limitations
Parekh <i>et al.</i> (2003) (1+)	Pre-operative consecutive recruitment of 38 US men scheduled to undergo RP between November 1998 and April 1999	Prior UI or faecal incontinence	Prospective randomization	Initial evaluation and two sessions (DRE and BF) pre-operatively and then physiotherapy every 3 weeks for 3 months post-operatively; home exercises for 6 months or longer	Control: no formal instruction; telephone call or meeting monthly	Number of pads used daily, urinary continence questionnaire at 6, 12, 16, 20, 28 and 52 weeks; continence defined as no pads used or one precautionary pad	Intervention group regained continence quicker at 12 weeks compared to control, no difference between groups at any other time point, 13% of total sample had severe UI at one year	The majority of patients recover by one year post-operatively, but this can be achieved sooner with PFMT	Intervention group older (mean = 61 years) than controls (mean = 55 years); small sample; did not assess control group's prior knowledge of PFMT
Sueppel <i>et al.</i> (2001) (1 -)	Pre-operative consecutive recruitment of 16 US men undergoing RP	None	No details given	Pre-operative instruction in PFMT, including two sessions of BF (anal probe); home exercises three times a day	Control: BF session 6 weeks post-operatively	Biofeedback (PRS 8900, InCare Medical Products, Libertyville, IL, USA) at 6 weeks, and 3, 6, 9 and 12 months; continence questionnaire, bladder diary, pad test (45 min, provocative)	At one year post-operatively, the early intervention group had less leakage on pad test compared with the controls; mean pad weight = 2.8 and 33.3 g, respectively	Starting BF sessions prior to RP improved outcomes	Descriptive statistics used because of small sample; missing data

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**Table 3.** *Continued*

Reference (level of evidence; SIGN 2004)	Recruitment	Inclusion criteria	Exclusion criteria	Randomization	Intervention	Comparison	Outcome measures	Main findings	Conclusion	Limitations
Van Kampen <i>et al.</i> (2000) (1++)	Post-operative consecutive recruitment of 102 Belgian men following RP from January 1995 to June 1996	Urinary incontinence on day 15 post-operatively, able to regularly attend hospital visits	None	Stratified randomization (previous TURP and volume of urine loss) with sealed envelopes	Once-weekly sessions of PFMT, rectal examination, BF and ES ( $n=7$ ) for as long as UI exists (maximum=1 year); home PFMT 90 times per day	Once-weekly placebo electrotherapy using surface electrodes	One- and 24-h pad tests, VAS, micturition charts done at 1, 6 and 12 month; 24-h pad test daily (when urine loss <2 g, 1-h test in clinic)	Continence scores significantly better in intervention group at 3 months; severe UI is rare one year post-operatively; UI occurred mostly during exertion	Therapy was most effective in the first 4 months, and therefore, it should be started as soon as possible post-operatively	Both groups received bladder training, which may have influenced the results
Wille <i>et al.</i> (2003) (1-)	Pre-operative consecutive recruitment of 139 German men undergoing RP from August 1999 to May 2001	Localized prostate cancer, willingness to participate	None	Authors state subjects randomized, but no details given	Group 1: PFMT and surface ES Group 2: PFMT, ES and BF (anal probe) for 15 min twice a day	Group 1: PFMT alone All: Verbal and written information from physiotherapist; three formal sessions	Twenty-minute provocative pad test, continence questionnaire; measured at baseline, 3 months and one year	No significant difference in continence rates between groups – all improved; by one year post-operatively, 83% continence; at 3 months, compliance had dropped to 56% (no difference between groups)	Electrical stimulation, and ES and BF-enhanced PFMT did not affect continence rates.	No details whether the data collector was blinded to treatment groups; no details of randomization or concealment

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Table 3. Continued

Reference (level of evidence; SIGN 2004)	Recruitment	Inclusion criteria	Exclusion criteria	Randomization	Intervention	Comparison	Outcome measures	Main findings	Conclusion	Limitations
Yokoyama <i>et al.</i> (2004) (2-)	Post-operative consecutive recruitment of 36 Japanese men undergoing RP from January 2001 to September 2002	Urinary incontinence	Less than 100 g pad weight on 24-h pad test on day 1 post-operatively	Authors state subjects randomized, but no details given	Group 1: ES 15 min daily for one month (anal probe) Group 2: ExMI for 20 min twice weekly for 2 months (sitting on chair with magnetic coil)	Pelvic floor muscle training taught with digital rectal examination, plus verbal and written information	Twenty-four-hour pad test, bladder diary, QoL questionnaire; measured at 1, 2 and 4 weeks, and 2, 3, 4, 5 and 6 months	Volume of urine leaked significantly less at one month between ES and control, and at 2 months between ExMI and control; no significant difference between groups at 3 months (pad test and QoL); overall, 86% pad-free at 6 months	Both ExMI and ES can offer earlier improved continence scores compared with PFMT alone	Small sample; no details of randomization, concealment or blinding; no indication of any dropouts or the exact numbers in each of the groups
Zhang <i>et al.</i> (2007) (1-)	Post-operative consecutive recruitment of 29 US men after RP who were screened for UI using the bladder control scale from the Barthel Index	Stage I-III prostate cancer, post-operative UI, consent to participate	None	Authors state subjects randomized, but no details given	Pelvic floor muscle training and support group (six, 90-min meetings, held twice a month, facilitated by a health psychologist)	Control: PFMT All: PFMT including BF session; home exercises two to three times per day for 5-10 min each session	Visual analogue scale, symptom questionnaire, IIRS; measured at baseline and 3 months	Significantly better compliance, improved continence and QoL scores, compared with intervention group controls	Addition of a support group enhances compliance, and improves continence and QoL scores compared with PFMT alone	Two dropouts (intention-to-treat not clear); univariate simple statistics ( $P \leq 0.1$ ); some significant differences in baseline characteristics between groups; no objective outcome measures used

The fourth study in this group was a small prospective RCT of 38 men that found a positive correlation between PFMT and improved continence (Parekh *et al.* 2003). The intervention group received regular formal sessions with a physiotherapist, which included biofeedback and home exercises, while the control group received no formal instruction. The outcome measures were the number of pads used and a continence questionnaire. There was a statistically significant improvement in continence scores in the intervention group at 12 weeks in comparison to the control group ( $P < 0.05$ ). However, there was no statistically significant difference between the groups at any of the other time intervals in the study (i.e. 6, 16, 20, 28 and 52 weeks). Parekh *et al.* (2003) concluded that the majority of patients will have regained continence by one year post surgery, but this result can be achieved more quickly with PFMT. The limitations of this study included the small sample size and the fact that the intervention group was significantly older than control group (mean ages = 61 and 55 years, respectively). Although the control group did not receive any formal instruction in PFMT, there was no assessment of the subjects' prior knowledge of PFMT or whether they had carried out self-taught exercises during the study period.

The fifth study in this group was a well-conducted prospective RCT of 125 men (Burgio *et al.* 2006). This survey compared subjects who underwent one pre-operative session of biofeedback training and a regime of home PFMT with a control group who received 'usual care' (i.e. advice to carry out a midstream stop). The outcome measures were bladder diaries, pad usage and QoL scores. The results showed a significant improvement in the intervention group compared with the control group in severe/continual leakage at 6 months ( $P = 0.04$ ), less pads used ( $P < 0.05$ ), and less leakage on cough ( $P = 0.003$ ) and sneeze ( $P = 0.02$ ). Interestingly, no significant differences were found in QoL scores, return to work or activities between groups. The limitations of this study include the lack of validity and reliability of pad usage as an outcome measure. It is difficult to ascertain the benefit of biofeedback training as an adjunct to PFMT, and it might have been useful to compare the intervention group with a group carrying out a similar regime of home PFMT without the initial session of biofeedback.

Five RCTs found no benefit from the treatment intervention (Mathewson-Chapman 1997;

Moore *et al.* 1999; Bales *et al.* 2000; Franke *et al.* 2000; Floratos *et al.* 2002).

An RCT of 53 men compared subjects who underwent PFMT with biofeedback (three times per week for 12 weeks) with a control group who received no treatment (Mathewson-Chapman 1997). The results showed that the intervention group regained continence at a mean of 51 days and the control group regained continence at 56 days. No statistical significant difference was found between the groups. The outcome measures included pad testing, the number of pads used, bladder diaries and the number of incontinence episodes. Both groups received training in 'the Knack' and lifestyle advice, which may have had an influence on the results. No raw data was published.

A single-blind RCT by Moore *et al.* (1999) of 63 subjects compared a control group who received written and brief verbal instructions on PFMT with subjects who underwent physiotherapy alone or physiotherapy and adjunctive ES therapy. The outcome measures included pad tests, the number of pads used, the number of episodes of leakage and three QoL scores. No statistical difference was found between the groups, although an improvement in symptoms was seen in all three sets of subjects. The authors concluded that the rapid improvement in all three groups may have masked any treatment benefit (mean time since surgery = 18.9 weeks). One possible limitation of this study is that 54% of the initial sample had pre-operative lower urinary tract symptoms.

A study of 100 men compared subjects who underwent a session of pre-operative biofeedback and PFMT with a control group who received written and brief verbal instructions on PFMT (Bales *et al.* 2000). Pad usage outcomes were gathered at 1, 2, 3, 4 and 6 months after surgery. At 6 months, there were no significant differences between groups ( $P = 0.596$ ); however, 94% of the intervention group and 96% of the control group were continent by this time. Limitations include the lack of detail given on the randomization process, no documentation of power calculations and the fact that the intervention group only received one session of biofeedback training.

Franke *et al.* (2000) carried out a small trial of 30 men that compared early post-operative biofeedback and PFMT with no treatment. The intervention group were given five, 45-min sessions of surface electromyography (EMG) biofeedback, home PFMT and advice. The outcome

**Table 4.** Characteristics of systematic reviews included in the literature review: (PFMT) pelvic floor muscle training; (RCT) randomized controlled trial; (TURP) transurethral resection of the prostate; (UI) urinary incontinence; (RP) radical prostatectomy; (TENS) transcutaneous electrical nerve stimulation; (ES) electrical stimulation; (ExMI) extracorporeal magnetic innervation; (BF) biofeedback; and (DRE) digital rectal examination

Reference (level of evidence; SIGN 2004)	Aim	Sample	Search	Study quality	Inclusion criteria	Exclusion criteria	Main findings	Conclusion	Limitations
Dorey (2005) (1 -)	To determine if PFMT had value as a conservative treatment in restoring normal pelvic floor function in men	Eleven RCTs, one Cochrane review	From 1980 to 2005: MEDLINE, CINAHL, AMED, EMBASE and Cochrane Library; keywords given, hand search done	Methodological quality examined and evidence statements based on a five-point hierarchical scale	Treatment before and after TURP and RP, and for post-micturition dribble; only RCTs; valid outcome measures (subjective and objective)	Non-RCTs	Type II evidence (strong evidence from at least one properly designed RCT of appropriate size) that PFMT is effective for an early return to continence following RP; no evidence of a BF enhanced treatment effect	Pelvic floor muscle training shown to significantly reduce UI after RP; a large, multi-centre RCT is needed to further explore use of PFMT as a first-line treatment for UI post RP	No details given on method used to evaluate individual studies; several author opinion statements given with no reference
Hunter <i>et al.</i> (2007) (1 + +)	To assess the effects of conservative management of UI after prostatectomy	Seventeen trials met criteria (15 post-RP, one post-TURP, one both)	Ranging from 1984 to 2006; Cochrane trials register, MEDLINE, CINAHL, EMBASE, ERIC and PsycLIT; hand search (including conference proceedings)	Papers reviewed by two authors	Randomized or quasi-randomized trials	Non-RCTs	Only one trial suggested benefits from PFMT for UI post-RP; clinical and statistical heterogeneity; use of TENS/ES inconclusive; no trials on lifestyle interventions identified	Majority of available trials of moderate quality; value of conservative treatments remains unproven; long-term UI may be managed by external penile clamp	Noted conflict of interest: one author was an investigator in three of the trials included

Continued

**Table 4. Continued**

Reference (level of evidence; SIGN 2004)	Aim	Sample	Search	Study quality	Inclusion criteria	Exclusion criteria	Main findings	Conclusion	Limitations
MacDonald <i>et al.</i> (2007) (1++)	To evaluate effectiveness of PFMT for UI after RP	Eleven RCTs met criteria	From 1966 to 2006: MEDLINE and Cochrane Library; hand search done	Models, scales and software used to determine concealment, intention-to-treat, lost to follow-up, risk reductions, confidence intervals and heterogeneity between studies	Studies enrolling men with UI post-RP or -TURP, randomized trials, trials with clinical outcomes	Non-English papers	Pelvic floor muscle training better than no treatment in improving continence; BF enhanced PFMT no better than oral or written instruction	Pelvic floor muscle training and/or BF hasten(s) return of continence compared with no treatment; further trials needed to look at the effectiveness of ES and ExMI; difficult to compare the results of the trials because of the level of heterogeneity found	Not all relevant databases searched
Moore & Dorey (1999) (2++)	To present an overview of current literature on UI in men, make suggestions for clinical practice and pose questions for future research	Eight trials	From 1976 to 1999: MEDLINE and CINAHL; manual search from 1850; hand search of conference proceedings	Authors describe some methodology, but no details given on evaluation of individual studies	English, all types of male UI (not just after prostate surgery)	None	PFMT with BF promising treatment option for UI in men; current research does not support ES as a routine intervention for post RP UI; general trend of rapid improvement in UI in first year post RP	Difficult to compare studies because of variations in methodology; future research needs to look at: pre-operative PFMT, whether biofeedback enhances PFMT and the role of ES	Some relevant databases not searched; no details on methods used to evaluate quality of papers; no exclusion criteria

*Continued*



Table 4. Continued

Reference (level of evidence; SIGN 2004)	Aim	Sample	Search	Study quality	Inclusion criteria	Exclusion criteria	Main findings	Conclusion	Limitations
Moore (2000) (2++)	To review the current literature on the use of ES in men with UI	Eight trials found	MEDLINE, CINAHL and Cochrane Library; comprehensive proceedings screened; hand search of reference lists; keywords given	Author describes some methodology, but no details given on evaluation of individual studies	Published articles and abstracts in English	Case series, studies involving men with spinal cord injuries, abstracts without control group	Primary role of ES appears to be in the treatment of urge UI; ES is a non-invasive and potentially useful tool; clinicians must question, challenge and test current practice	Evidence for ES in the treatment of stress UI in men is weak, RCTs are needed to determine full benefit	Some relevant databases not searched; no details of methods used to evaluate quality of papers
Nahon <i>et al.</i> (2006) (1++)	To determine the evidence to support the use of conservative measures in the treatment of UI after prostate surgery	Forty-nine articles ranging from 1976 to 2006	Fourteen databases searched; keywords given; no restrictions on time period	Authors used a recognized methodological tool and tested inter-rater reliability	Articles on PFMT and/or BF, electrotherapy, TENS, and behavioural therapy on men after prostate surgery	Articles on continence aids, measures a continence nurse cannot apply, invasive measures, articles on general ageing process	Evidence shows some support for use of PFMT; trend towards BF as an adjunct to PFMT; expert opinion divided over use of ES for patients with previous cancer; usefulness of TENS not proven; no real evidence base for lifestyle changes	All areas need more good-quality research; most of the current literature centres on expert consensus and personal opinion	One of the authors also wrote many of the papers included in the review, possibly resulting in bias; no indication of how many authors read each paper

Continued

**Table 4. Continued**

Reference (level of evidence; SIGN 2004)	Aim	Sample	Search	Study quality	Inclusion criteria	Exclusion criteria	Main findings	Conclusion	Limitations
Wilson <i>et al.</i> (2005) (1++)	To contribute to the 3rd International Consultation on Incontinence	Twelve relevant randomized papers identified	Major databases covering past 10 years; tables of contents of relevant journals in preceding 3 months	Modified Oxford system used for evaluating evidence; recommendations based on five levels of evidence and four grades of recommendation	Papers or abstracts published or accepted for publication in peer-reviewed journals	Papers in non-peer-reviewed journals	Reasonable to recommend healthy lifestyle choices; not clear whether pre-operative PFMT improves continence recovery; modest benefit from pre- and post-operative PFMT in the short term; no conclusions can be drawn regarding PFMT taught by DRE; PFMT with BF appears to improve early outcomes, but has no benefit in the long term; some men may benefit from ES more than others; insufficient evidence to determine if ES is better than ExM	Further research needed regarding the effects of caffeine and constipation on UI, pre- versus post-operative PFMT, effects on post-operative PFMT, support groups, effects of ES in male patients, comparison of ES and ExMI	Summary sheet of recommendations may be useful

measures were 48-h pad testing and bladder diaries. The final outcomes were measures 24 weeks after surgery. The results show no significant difference between the groups, but a trend in favour of the control group was noted. At 6 months, 87% of the total sample were pad-free. Some limitations of the study are the small sample size, that no details were given of the randomization process and the lack of documented baseline data.

The final study in this group was a small RCT of 42 men comparing subjects who underwent surface EMG biofeedback with a control group who received a digital rectal examination and verbal instructions on PFMT (Floratos *et al.* 2002). The intervention group underwent 15 formal sessions of biofeedback and were advised on home PFMT. Outcomes were measured at 1, 2, 3 and 6 months, and included the 1-h pad test and continence questionnaires. The level of incontinence declined in both groups. The control group had less urine loss, although this was not statistically significant. The total objective continence rate at 7 months was 90%. Some possible limitations of this study are that the home exercise instructions differed between groups, no baseline data were provided and the data were only supplied in qualitative percentages.

There were significant differences in the materials and methodology used in all 10 RCTs, which makes comparisons between these studies difficult. Three trials started treatment pre-operatively (Bales *et al.* 2000; Parekh *et al.* 2003; Burgio *et al.* 2006), and of the seven trials that started treatment post-operatively, the time at which intervention started ranged between 7 and 16 days following catheter removal and 8 weeks after surgery; one study did not provide this information (Floratos *et al.* 2002).

The control groups also varied considerably between the studies. In five trials, the controls received no intervention (Mathewson-Chapman 1997; Franke *et al.* 2000; Parekh *et al.* 2003; Filocamo *et al.* 2005; Manassero *et al.* 2007). Verbal and written instructions on PFMT were given as a control in another two trials (Moore *et al.* 1999; Bales *et al.* 2000), with the addition of a digital rectal examination in the study by Floratos *et al.* (2002) and the inclusion of advice on practising a midstream stop in Burgio *et al.* (2006).

The inclusion and exclusion criteria also varied considerably between the studies. Many detailed comprehensive lists of inclusion and

exclusion criteria, whilst some reported very scant lists or none at all. Of particular interest is that some of the trials excluded men with pre-operative urinary incontinence whilst some did not. This could be a significant barrier to comparing the results.

There was significant variation in the outcome measures used. Seven of the studies used pad tests ranging from 1 h (Van Kampen *et al.* 2000; Floratos *et al.* 2002; Filocamo *et al.* 2005) to 24 h (Mathewson-Chapman 1997; Moore *et al.* 1999; Van Kampen *et al.* 2000; Filocamo *et al.* 2005) to 48 h (Franke *et al.* 2000). The accuracy of pad testing can be difficult to assess (Lose *et al.* 1998). The 1-h pad test is a clinical test that measures urine lost under standardized conditions. The reported benefits of this short-term measure are that it is easy and cheap to carry out, patient compliance can be monitored, and potential errors from evaporation of urine can be eliminated (Donnellan *et al.* 1997; Ryhammer *et al.* 1999). However, 1- and 2-h pad testing have been shown to be poor predictors of incontinence severity (Walters *et al.* 1990). The longer-term measures, such as the 24-h pad test, are carried out in the home and reflect urine loss in the natural environment. In a well-designed prospective observational study carried out on 108 women, this test was found to have good repeatability (Karantanis *et al.* 2005). Although authors have stated that the usefulness of pad tests is unclear, and can be influenced by patient anxiety and compliance (SIGN 2004b), these measures seem to offer the possibility of quantifying the degree of incontinence (Lose *et al.* 1998).

Only three studies used a validated QoL measure (Moore *et al.* 1999; Filocamo *et al.* 2005; Burgio *et al.* 2006). Urinary incontinence is consistently associated with producing a significant negative impact on QoL and UI after RP is a significant cause of post-operative morbidity (Harris 1997; SIGN 2004b). Men with post-operative lower urinary tract symptoms have shown higher depression scores, can become socially reclusive and dependent on others, and can experience reduced self-esteem (Assad 2000; McGlynn *et al.* 2004; Moore & Gray 2004). The effects of interventions on QoL are probably one of the most important outcome measures (Nordling *et al.* 1998). It is important that research focuses on QoL not only immediately after surgery, but also in the longer term since QoL scores may decrease as the time following surgery increases because a patient's appreciation

of QoL may change (Grise & Thurman 2001). A survey of 156 US men reported that 74% felt that UI was an important issue to resolve, irrespective of the time after surgery (Palmer *et al.* 2003).

Seven of these trials used the number of pads per day as an outcome measure (Mathewson-Chapman 1997; Moore *et al.* 1999; Bales *et al.* 2000; Floratos *et al.* 2002; Parekh *et al.* 2003; Filocamo *et al.* 2005; Burgio *et al.* 2006). The threshold for changing pads may differ between individuals, and therefore, using the number of pads as a measure of incontinence may not be wholly accurate (Donnellan *et al.* 1997). A retrospective chart review of male and female patients showed that pads per day usage measured only 38% of the variability of UI volume and concluded that this was not a reliable measure of continence status (Dylewski *et al.* 2007).

Another significant barrier to comparing these trials is the variation in the definition of continence. Two trials defined continence as using no pads (Mathewson-Chapman 1997; Franke *et al.* 2000), three trials defined it as using no pads or only pad one per day (Bales *et al.* 2000; Floratos *et al.* 2002; Parekh *et al.* 2003), and one study defined continence as using one precautionary pad per day (Filocamo *et al.* 2005). Several studies used pad testing as a means of defining continence. A loss of less than 1 g of urine on a 1-h pad test was the definition of continence in one trial (Floratos *et al.* 2002), and two studies defined continence as 2 g or less of urine loss on a 24-h pad test (Moore *et al.* 1999; Manassero *et al.* 2007). The study by Van Kampen *et al.* (2000) was similar in that patients were deemed to be continent with a loss of no more than 2 g of urine on both the 24-h and 1-h pad tests, and no reported leakage in 3 days. One trial used three consecutive 1-day bladder diaries or a 7-day diary showing no leakage as their definition of continence (Burgio *et al.* 2006).

#### *Post-operative pelvic floor muscle training versus another treatment*

Three RCTs were identified in this category (Wille *et al.* 2003; Yokoyama *et al.* 2004; Zhang *et al.* 2007).

A trial of 139 men recruited before surgery compared PFMT and ES, and PFMT, ES and biofeedback with formal PFMT (Wille *et al.* 2003). The primary outcome measure was a 20-min provocative pad test. This test has been shown to be significantly more sensitive when compared with the 1-h pad test (Wu *et al.* 2006).

Wille *et al.*'s (2003) results showed no significant differences between groups measured at 3 months and 1 year after RP. There was no statistical difference in self-reported compliance with treatment between groups. Interestingly, only 56% of the total sample were compliant with treatment at 3 months, but no reasons were given for this finding.

A Japanese study of 36 men recruited after surgery compared ES and extracorporeal magnetic innervation (ExMI) with PFMT taught using digital rectal examination (Yokoyama *et al.* 2004). The subjects received 15 min of ES daily or 20 min of ExMI twice weekly. The outcome measures included a 24-h pad test and the Urinary Incontinence-Specific Quality of Life Instrument. This QoL measure has been shown to be valid and reproducible (Donovan *et al.* 2005). The results showed that the volume of urine lost at 1 and 2 months was significantly less for the ES and control groups ( $P < 0.05$ ), and the ExMI and control groups ( $P < 0.05$ ), respectively. At 3 months, there was no significant difference. Subjects who had  $< 100$  g loss on day 1 (24-h test) were excluded. The limitations included the small sample size and the fact that there was no indication of the exact number of subjects in each group. It was not clear if the ES and ExMI groups also carried out PFMT, and there was no indication of the exercise regime for the PFMT group.

A pilot study of 29 men examined the effect of PFMT with the addition of a support group compared with PFMT alone on QoL scores following prostatectomy (Zhang *et al.* 2007). The support group consisted of a twice-monthly meeting facilitated by a health psychologist over 3 months. The outcome measures were subjective and included a VAS, a symptom questionnaire and the Illness Intrusiveness Rating Scale, which were measured at baseline and 3 months. The subjects allocated to PFMT and support group attendance showed significantly better compliance ( $P = 0.077$ ), decreased pad use ( $P = 0.057$ ), improved continence scores ( $P = 0.011$ ) and improved QoL scores ( $P = 0.037$ ) compared with subjects assigned to PFMT alone. The level of significance was set at  $P \leq 0.10$ . There were two dropouts in this study and intention-to-treat was not clear. Further limitations include the small sample size and that fact that there were some significant differences in the baseline characteristics between groups.

None of the above RCTs gave details of randomization, and therefore, the results may

need to be viewed with some caution. It has been suggested that studies should be classed as controlled clinical trials rather than RCTs if the authors do not provide adequate details of randomization (SIGN 2004a).

#### *Post-operative versus pre-operative pelvic floor muscle training*

Only one RCT was identified on this subject (Sueppel *et al.* 2001). A study of 16 men compared pre-operative PFMT, including biofeedback and home exercises, with PFMT and biofeedback begun 6 weeks after surgery. At 1 year after RP, the pre-operative exercise group showed less leakage on pad testing (45-min provocative test) compared with the post-operative group (mean pad weights=2.8 and 33.3 g, respectively). Unfortunately, this was a very small sample and only descriptive statistics were used. Once again, no details were given regarding the method of randomization.

#### *Systematic reviews and guidelines*

A systematic review of 11 RCTs and a Cochrane review showed strong evidence that PFMT after RP can promote an early return of continence (Dorey 2005). There was more modest support for this treatment from other reviews (Moore & Dorey 1999; Wilson *et al.* 2005; Nahon *et al.* 2006; Hunter *et al.* 2007; MacDonald *et al.* 2007). All the relevant reviews identified by the present authors showed some evidence to support PFMT, but a comprehensive review of the literature by the Cochrane Collaboration suggested that conservative treatment for UI after RP remains unproven (Hunter *et al.* 2007).

One review found no evidence for the use of ES for male UI (Moore & Dorey 1999). However, one of the above authors carried out a review specifically looking at ES and concluded that it could be effective in UUI, but evidence for its use in SUI was weak (Moore 2000). Wilson *et al.* (2005) concluded that some men may benefit from ES, but was not able to deduce whether ES was more effective than ExMI.

Two reviews concluded that there was no evidence that biofeedback enhanced the effect of PFMT (Dorey 2005; MacDonald *et al.* 2007). One other showed a positive trend towards biofeedback as an adjunct to PFMT (Nahon *et al.* 2006), while yet another concluded there was no benefit from PFMT enhanced with biofeedback in the long term (Wilson *et al.* 2005).

The quality of all seven systematic reviews was good. Some limitations were that three reviews

did not give exact details of the methods used to appraise the studies (Moore & Dorey 1999; Moore 2000; Dorey 2005), a conflict of interest was noted in two others (Nahon *et al.* 2006; Hunter *et al.* 2007) and some relevant databases were not searched in three reviews (Moore & Dorey 1999; Moore 2000; MacDonald *et al.* 2007).

*Management of Urinary Incontinence in Primary Care: A National Clinical Guideline* (SIGN 2004b) recommended that PFMT should be considered for patients following radical prostate surgery, particularly in the first few months after the operation.

*Prostate Cancer: Diagnosis and Treatment* (NICE 2008) advocated that men with bothersome urinary symptoms should have access to specialist continence services, which may include PFMT.

#### **Conclusion**

There are many obstacles in reviewing the literature, including the heterogeneous nature of the RCTs with regard to outcome measures, definitions, inclusion/exclusion criteria (e.g. pre-operative urinary symptoms), time since surgery, surgical technique and treatment protocols. Therefore, it is very difficult to draw conclusions based on the trials discussed in the present review (Moore & Dorey 1999; Hunter *et al.* 2007). All but one RCT gave details of the PFMT regime employed and there was a wide variation in the protocols documented. There appears to be a need for a standardized PFMT regime (Dorey 2005), but further investigation into this is beyond the scope of the present paper.

Safety issues around the use of ES were not discussed frequently in the literature. None of the trials using ES as an intervention made any reference to safety issues. The Chartered Society of Physiotherapy guidelines for the physiotherapy management of female SUI (Laycock *et al.* 2001) state that the presence of abnormal or malignant cells in the pelvis or abdomen is a contraindication to ES. Although there is insufficient evidence to suggest that ES poses any risk, many therapists are unwilling to use this intervention in men following RP (Wilson *et al.* 2005). Through discussions with colleagues, the present authors found that many therapists concur with this sentiment.

At present, there appears to be weak to moderate evidence for the use of PFMT for UI



after RP. Irrespective of management, the spontaneous recovery of symptoms in the first year after surgery is beyond doubt (Moore & Dorey 1999; SIGN 2004b; Wilson *et al.* 2005; Hunter *et al.* 2007), but the evidence points towards this recovery being quicker with specific intervention. There is a general consensus that further research is needed, specifically investigations into the effects of support groups, psychological support and prevention strategies (Peyromaure *et al.* 2002; Rigby 2003; SIGN 2004b). Future research must examine not only the direct costs associated with UI, but also the indirect expenses related to major issues such QoL. Only three of the RCTs discussed in the present review used a validated QoL questionnaire. The extended economic implications of men suffering from UI (e.g. the inability to return to work) must also be explored.

The literature shows that spontaneous recovery of continence can occur in patients within 1 year. However, because UI can have a devastating impact on a patient's QoL, it is the present authors' opinion that, if recovery time can be shortened with intervention, then treatment should be offered to all men with UI following RP. Therapists should continue to use clinical judgement along with the best available evidence to focus rehabilitation on the needs and realistic goals of the patient.

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